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(stamp:) OIPE JC109 JAN 2 8 2004 PATENT & TRADEMARK OFFICE

FEE TRANSMITTAL
for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 130

Complete if Known	
Application Number	10/747,974
Filing Date	December 30, 2003
First Named Inventor	George M Levinson
Examiner Name	(TBA)
Art Unit	(TBA)
Attorney Docket No.	06335.00007

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit Account Number: **19-0733**

Deposit Account Name: **Banner & Witcoff, LTD.**

The Director is authorized to: (check all that apply)
☒ Charge fee(s) indicated below ☒ Credit any overpayments
☒ Charge any additional fee(s) during the pendency of this application
☐ Charge fee(s) indicated below, **except for the filing fee**
to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filling fee	

SUBTOTAL (1) ($) 0

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

	Extra Claims		Fee from below		Fee Paid
Total Claims	- ** =	0	X	=	0
Independent Claims	- ** =	0	X	=	0
Multiple Dependent			X	=	0

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) 0

**or number previously paid, if greater; For Reissues, see above*

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet.	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive – unavoidable	
1453	1,330	2453	665	Petition to revive – unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	130
1807	50	1807	50	Processing fee under 37 CFR 1.17 (q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR § 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR § 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid   SUBTOTAL (3) ($) 130

SUBMITTED BY

					Complete (if applicable)
Name (Print/Type)	Robert H. Resis	Registration No. (Attorney/Agent)	32,168	Telephone	(312) 463-5000
Signature	*(signature)*			Date	January 28, 2004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Attorney Docket No. 06335.00007)

In the Application of:)	
)	
George M. Levinson et al.)	
)	Group Art Unit: (TBA)
Serial No.: 10/747,974)	
)	Examiner: (TBA)
Filed: December 30, 2003)	
)	
For: System, Method, and Computer-Readable)	
Medium for Collection of Environmental)	
Data and Generation of User Report for)	
Compliance with FDA Requirements)	

PETITION TO MAKE SPECIAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

Sir:

Applicants respectfully petition to make the above-cited application special for accelerated

examination pursuant to 37 CFR 1.102 and MPEP 708.02 (VIII). The above-cited application has

not received any examination by the examiner. The Patent Office is authorized to charge the

required fee for this petition to make special as set forth in 37 CFR 1.17(h) to Account No. 19-0733.

All of the claims are directed to a single invention, or if the Office determines that all of the claims

presented are not obviously directed to a single invention, the Applicants will make an election

without traverse as a prerequisite to the grant of special status. A pre-examination search was made

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by a prior art search firm, listing the field of search by class and subclass, publication, Chemical

Abstracts, foreign patents, etc. The field of Search included:

FIELD OF SEARCH

CLASS	SUBCLASS
422	62
700	90, 108, 109, 111, 266, 276, 277, 299, 300

Attached is a copy of each reference found in the search (Reference Nos. 1-15), and a copy of

U.S. Patent No. 5,838,906, cited in the application (Reference No. 16), and a copy Reference Nos.

17-21, which refer to the Environmental Monitoring Software System (EMSS), owned by the

assignee of the application, and which is cited in the application. The following is a detailed

discussion of the references, which identifies with the particularity required by 37 CFR 1.111 (b)

and (c), how the claimed subject matter is patentable over the references.

1. U.S. Patent No.4,298,955 discloses a system for detecting and analyzing deviations

from normal in the operating conditions of a process, for example a chemical manufacturing process.

The system comprises transducers positioned to detect a plurality of operating parameters and

generate signals representative of the said parameters. A processing device is connected to receive

the signals and programmed to analyze the signals on the basis of a decision table having columns

each of which represents a different combination of operating parameter values. Each column has

associated therewith a value representing the seriousness of the deviation represented by the

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combination of values. Means are provided for displaying, storing and/or recording the nature of each deviation analyzed by the processing device and the value associated therewith. Systems for transmitting data from transducers to a receiver and for analyzing data are also provided.

This reference does not teach the present invention, for example a data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the environmental data, and generate a user report of the environmental data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler, facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements.

2.   U.S. Patent No. 5,103,391 discloses a highly distributed direct digital process control system for use in controlling a fully distributed process includes at least one device controller independently monitoring and controlling a plurality of external devices for performing a complete process. One or more data concentrator units are connected to the controllers for collecting information from each controller as well as directing updated control information to specific controllers. A central information processing means is connected to the data concentrator for displaying information received from the data concentrator. The central information processing means is capable of updating control information used by specific controllers.

This reference does not teach the present invention, for example a data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the environmental data, and generate a user report of the environmental data, the equipment selected

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from the group consisting of a particle counter, organism identification system, viable air sampler, facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements.

3. U.S. Patent No. 5,691,895 discloses a comprehensive, generic mechanism models, monitors, controls and optimizes manufacturing as an on-line, real-time system employing statistical analysis and mathematical techniques with feedback and forward information for local control and global optimization. Manufacturing is treated as a hierarchy of processes which are modeled, controlled, optimized and managed via four interacting networks; an application modeling network, a local control network, a global optimization network, and an implementation/management network. Of these four networks, only the application modeling network is application dependent. The functions of the other three networks are application independent. All manufacturing processes, from simple process steps through manufacturing sectors and lines, to complete factories, are treated identically, thereby simplifying computational complexity. A minimal set of parameters is thereby obtained at any manufacturing level, which reduces a complex manufacturing process to a manageable form. Outputs of lower level processes in the hierarchy become input process variables for higher levels. Process models are developed and updated via on-line data analysis, and are used to evaluate process status and improvement path.

This reference does not teach the present invention, for example a data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the environmental data, and generate a user report of the environmental data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler,

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facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements.

4.   U.S. Patent No. 5,719,796 discloses a statistical simulation of a semiconductor fabrication process is performed in parallel with the actual process. Input parameters derived from a probability density function are applied to the simulator which, in turn, simulates an actual fabrication process which is modeled as a probability density function. Each simulation step is repeated with a random seed value using a Monte Carlo technique, a trial-and-error method using repeated calculations to determine a best solution to a problem. The simulator generates an output in the form of a probability distribution. The statistical simulation uses single-step feedback in which a simulation run uses input parameters that are supplied or derived from actual in-line measured data. Output data generated by the simulator, both intermediate output structure data and WET data, are matched to actual in-line measured data in circumstances for which measured data is available. The probability density structure of the simulator is adjusted after each simulation step so that simulated data more closely matches in-line measured data.

This reference does not teach the present invention, for example a data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the environmental data, and generate a user report of the environmental data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler, facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements.

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5.   U.S. Patent No. 5,787,021 discloses an information system for production control wherein measured data from many test facilities is controlled, stored, and, if necessary, processed in a central data base. Via two-way data links, various data users can access the stored data and use this data for their own purposes. Thus it is possible, for example, to retrieve production figures of individual products or entire product ranges, complied statistics, calculate costs, determine yields, and the like. Access by the individual data users to the data base takes place via a terminal or a personal computer, with which nearly every work place is equipped and which are electronically interconnected via a data network for the exchange of data.

This reference does not teach the present invention, for example a data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the environmental data, and generate a user report of the environmental data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler, facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements.

6.   U.S. Patent No. 5,798,945 discloses small modules directly situated at power outlets in buildings, that contain at least one sensor gather and report local environmental data such as temperature, humidity, carbon dioxide concentration, motion, particulate matter concentration, carbon monoxide, methane, or other parameters. The local modules report data back over existing building power wiring to a central unit. The central unit may store or reduce data for reporting over to a computer over a conventional RS-232 link. The data can be used to prove compliance with

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environmental and safety regulations and requirements or used to control HVAC equipment. Also, the data can be displayed or used with energy price tier systems.

This reference does not teach the present invention, for example a data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the environmental data, and generate a user report of the environmental data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler, facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements.

7.   U.S. Patent No. 5,862,054 discloses a method to monitor process parameters from multiple process machines to provide real time statistical process control (SPC). The particular implementation was derived from ion implantation of wafers, but has wide applicability where there are a number of process machines having a number of process parameters and close continuous sampling of data is required. The process parameters are collected on a single computer over a single RS 485 network, and each parameter is analyzed and displayed separately for each process and process machine. Statistical variables like Cp and Cpk are calculated and presented on the computer screen along with graphs of the various parameters for a particular process machine. Data is aged out of the computer to an archival data base under the control of a manufacturing information system and connected to a company wide network.

This reference does not teach the present invention, for example a data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the

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environmental data, and generate a user report of the environmental data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler, facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements.

8.　　U.S. Patent No. 5,892,690 discloses an environment monitoring system and method for systematically and continuously monitoring an environment. The system and method includes a data acquisition system which is programmed to systematically collect environment data for a site. The data acquisition system includes sensors coupled to a data storage device having a remote access device for electronic access from a remote system. Data may be uploaded to a remote database for storing environment data from many sites. The remote database includes a remote access device so that the data storage devices of various data acquisition sites can be electronically coupled to the remote database for centralized data collection and storage.

This reference does not teach the present invention, for example a data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the environmental data, and generate a user report of the environmental data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler, facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements.

9.　　U.S. Patent No. 6,163,732 discloses systems, methods and computer program products to determine compliance of a chemical product to be manufactured to government

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regulations that govern the manufactured product. According to the invention, the chemical compositions that are present in the chemical product to be manufactured are ascertained. The chemical compositions so ascertained are compared to a stored set of government regulatory standards related to the chemical compositions to determine compliance. Accordingly, compliance with complex government regulations governing chemical products can be determined.

This reference does not teach the present invention, for example a data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the environmental data, and generate a user report of the environmental data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler, facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements.

10.   U.S. Patent No. 6,523,045 discloses a method for managing information about a manufacturing operation uses factory screens, shop floor screens and/or the like of a shop floor control graphical user interface. The factory screen graphically represents a factory. The shop floor screens represent different shop floors or other areas of the factory. These areas of the factory are represented by selectable icons, positioned within the factory screen at locations corresponding to the locations of the represented areas within the factory. Each shop floor screen depicts the general appearance of one of the areas of the factory and the factory elements of that area of the factory. Icons representing factory elements are positioned within the shop floor screens at locations corresponding to the locations of the represented factory elements within the corresponding shop

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floor. Icons representing machines and storage locations include graphics depicting the appearance of the represented machine or storage location.

This reference does not teach the present invention, for example a data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the environmental data, and generate a user report of the environmental data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler, facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements.

11.   U.S. Patent No. 6,539,271 discloses a quality management system and computer based process for managing quality. The quality management system includes a set of networked operator stations for entering data including critical to quality customer information and information relating to the equipment to be monitored on a quality basis. The system further includes an application server on the network for running the programs of the system such as critical to quality setup, report generation, logging to the database, and maintenance events. A database server is further included on the network for storing the local database. A web server holding a capability warehouse connects to the local database over a web connection. The process for managing the quality of the monitored electrical equipment includes sending process capability data from the local database to the capability warehouse, updating an entitlement database embedded in the capability warehouse, delivering new schema information to the local database from the entitlement database, and reporting information to the customer at an operator station via an automatic or requested report.

This reference does not teach the present invention, for example a data management system

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having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the environmental data, and generate a user report of the environmental data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler, facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements.

12.   U.S. Patent No. 5,631,839 discloses a device for controlling a complex manufacturing process. The device comprises at least one remote monitor designed to receive in real time signals through a local area network making it possible to analyze the state of the manufacturing process. There are a plurality of sensors, each of the sensors transforming the value of an associated parameter of the manufacturing process so as to produce an analogue signal. There is an analogue to digital converter associated with each of the sensors for producing a succession of numerical values representing the instantaneous state over time of the corresponding parameter. Each of the converters is interfaced with the local area network. A processor for processing the numerical values and comparing them with given reference values is also connected to the local area network such that the local area network conveys the result of the comparison to the remote monitor or monitors and also conveys the information coming from the analogue to digital converter to the processing means.

This reference does not teach the present invention, for example a data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the environmental data, and generate a user report of the environmental data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler,

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facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements.

13.   U.S. Patent No. 6,437,692 discloses a system for monitoring a variety of environmental and/or other conditions within a defined remotely located region. In accordance with one aspect of the invention, a system is configured to monitor utility meters in a defined area. The system is implemented by using a plurality of wireless transmitters, wherein each wireless transmitter is integrated into a sensor adapted to monitor a particular data input. The system also includes a plurality of transceivers that are dispersed throughout the region at defined locations. The system uses a local gateway to translate and transfer information from the transmitters to a dedicated computer on a network. The dedicated computer, collects, compiles, and stores the data for retrieval upon client demand across the network. The computer further includes means for evaluating the received information and identifying an appropriate control signal, the system further including means for applying the control signal at a designated actuator.

This reference does not teach the present invention, for example a data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the environmental data, and generate a user report of the environmental data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler, facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements.

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14.   U.S. Patent No. 6,574,522 discloses a system and method for handling quality control data for a manufacturing process among a main computer and a plurality of remote computers, including the steps of establishing a connection between at least one of the remote computers and the main computer via a web browser, inputting quality control data of the manufacturing process from the remote computer into a database of the main computer via the web browser, performing a statistical analysis on the quality control data input into the main computer, and posting results of the statistical analysis on a web site of the main computer accessible to the remote computers through the web browser.

This reference does not teach the present invention, for example a data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the environmental data, and generate a user report of the environmental data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler, facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements.

15.   U.S. Patent No. 6,604,023 discloses environmental indicators computed for a particular environment and converted into a transmittable data format. Each of the environmental indicators is computed by electronic environmental measurement device from among multiple diverse electronic environmental measurement devices. Environmental indicators are transmitted to a portable data processing system associated with a user, which analyzes each of the environmental indicators according to an environment sensitivity profile stored at the portable data processing system for the user. Control signals are determined by the portable computer system for adjusting

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multiple environment control systems that control the particular environment in response to the analysis, such that a particular environment is temporarily managed by a portable data processing system according to environmental sensitivities of a particular user located within that particular environment.

This reference does not teach the present invention, for example a data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the environmental data, and generate a user report of the environmental data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler, facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements.

16.   U.S. Patent No. 5,838,906 discloses a system allowing a user of a browser program on a computer connected to an open distributed hypermedia system to access and execute an embedded program object. The program object is embedded into a hypermedia document much like data objects. The user may select the program object from the screen. Once selected the program object executes on the user's (client) computer or may execute on a remote server or additional remote computers in a distributed processing arrangement. After launching the program object, the user is able to interact with the object as the invention provides for ongoing interprocess communication between the application object (program) and the browser program. One application of the embedded program object allows a user to view large and complex multi-dimensional objects from within the browser's window. The user can manipulate a control panel to change the viewpoint used to view the image. The invention allows a program to execute on a remote server or other computers to calculate

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the viewing transformations and send frame data to the client computer thus providing the user of the client computer with interactive features and allowing the user to have access to greater computing power than may be available at the user's client computer.

This reference does not teach the present invention, for example a data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the environmental data, and generate a user report of the environmental data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler, facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements.

17.   Compliance Software Solutions Corp. web page description of its Environmental Monitoring Software System (EMSS) (3 sheets), located at http://www.csoftsol.com/emss.html. The Environmental Monitoring Software System (by Compliance Software Solutions Corp. of Vernon Hills, Illinois, the assignee of the present invention), provides a cost effective and efficient means to manually enter into a computer database program the presence of viable microbiological organisms, the presence of particulates and other environmental conditions within the facility, such as humidity, pressure, temperature, water quality (e.g., pH, conductivity, total organic content (TOC), endotoxin, coliform, and metals), and the respective amounts of different materials involved in the manufacture of the end product(s). Thus, this system provides a means to access and document facility operations and store and trend data to ensure that the environmental control systems of a facility are operating as intended. This system is particularly useful for pharmaceutical, biotechnology, and medical device

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manufacturers, who must comply with strict quality control requirements of governmental bodies. This system meets the requirements of 21 CFR Part 11.

This reference does not teach the present invention, for example a data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the environmental data, and generate a user report of the environmental data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler, facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements.

18. BD Diagnostic Systems, Industrial web page description of the Environmental Monitoring Software System (EMSS) of Compliance Software Solutions Corp. (2 sheets), located at http://www.bd.com/contentmanager/b_article.asp?ContentID=2655&d=&s=. The Environmental Monitoring Software System (by Compliance Software Solutions Corp. of Vernon Hills, Illinois, the assignee of the present invention), provides a cost effective and efficient means to manually enter into a computer database program the presence of viable microbiological organisms, the presence of particulates and other environmental conditions within the facility, such as humidity, pressure, temperature, water quality (e.g., pH, conductivity, total organic content (TOC), endotoxin, coliform, and metals), and the respective amounts of different materials involved in the manufacture of the end product(s). Thus, this system provides a means to access and document facility operations and store and trend data to ensure that the environmental control systems of a facility are operating as intended. This system is particularly useful for pharmaceutical, biotechnology, and medical device

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manufacturers, who must comply with strict quality control requirements of governmental bodies. This system meets the requirements of 21 CFR Part 11.

This reference does not teach the present invention, for example a data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the environmental data, and generate a user report of the environmental data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler, facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements.

19.   BD Diagnostic Systems, Industrial web page description of the Environmental Monitoring Software System (EMSS) of Compliance Software Solutions Corp. (3 sheets), located at http://www.bd.com/industrial/Catapult/BDCatapultv4n1.pdf.   The Environmental Monitoring Software System (by Compliance Software Solutions Corp. of Vernon Hills, Illinois, the assignee of the present invention), provides a cost effective and efficient means to manually enter into a computer database program the presence of viable microbiological organisms, the presence of particulates and other environmental conditions within the facility, such as humidity, pressure, temperature, water quality (e.g., pH, conductivity, total organic content (TOC), endotoxin, coliform, and metals), and the respective amounts of different materials involved in the manufacture of the end product(s). Thus, this system provides a means to access and document facility operations and store and trend data to ensure that the environmental control systems of a facility are operating as intended. This system is particularly useful for pharmaceutical, biotechnology, and medical device

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manufacturers, who must comply with strict quality control requirements of governmental bodies. This system meets the requirements of 21 CFR Part 11.

This reference does not teach the present invention, for example a data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the environmental data, and generate a user report of the environmental data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler, facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements.

20.   Compliance Software Solutions Corp. web page description of its Environmental Monitoring Software System (EMSS), in connection with 21 CFR Part 11 Compliance Assessment (4 sheets), located at www.csoftsol.com/21CFRPart11FinalStatement.pdf. The Environmental Monitoring Software System (by Compliance Software Solutions Corp. of Vernon Hills, Illinois, the assignee of the present invention), provides a cost effective and efficient means to manually enter into a computer database program the presence of viable microbiological organisms, the presence of particulates and other environmental conditions within the facility, such as humidity, pressure, temperature, water quality (e.g., pH, conductivity, total organic content (TOC), endotoxin, coliform, and metals), and the respective amounts of different materials involved in the manufacture of the end product(s). Thus, this system provides a means to access and document facility operations and store and trend data to ensure that the environmental control systems of a facility are operating as intended. This system is particularly useful for pharmaceutical, biotechnology, and medical device

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manufacturers, who must comply with strict quality control requirements of governmental bodies. This system meets the requirements of 21 CFR Part 11.

This reference does not teach the present invention, for example a data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the environmental data, and generate a user report of the environmental data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler, facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements.

21.   Compliance Software Solutions Corp. web page description of its Environmental Monitoring   Software   System   (EMSS)   (168   sheets),   located   at www.csoftsol.com/CSSCPresBinder.pdf. The Environmental Monitoring Software System (by Compliance Software Solutions Corp. of Vernon Hills, Illinois, the assignee of the present invention), provides a cost effective and efficient means to manually enter into a computer database program the presence of viable microbiological organisms, the presence of particulates and other environmental conditions within the facility, such as humidity, pressure, temperature, water quality (e.g., pH, conductivity, total organic content (TOC), endotoxin, coliform, and metals), and the respective amounts of different materials involved in the manufacture of the end product(s). Thus, this system provides a means to access and document facility operations and store and trend data to ensure that the environmental control systems of a facility are operating as intended. This system is particularly useful for pharmaceutical, biotechnology, and medical device manufacturers, who must

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comply with strict quality control requirements of governmental bodies. This system meets the requirements of 21 CFR Part 11.

This reference does not teach the present invention, for example a data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the environmental data, and generate a user report of the environmental data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler, facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements.

In view of the foregoing, the Applicants respectfully request that the Petition to Make Special be granted and that the application be advanced for examination.

Respectfully submitted,

BANNER & WITCOFF, LTD.

Dated: January 28, 2004   By: _____

Robert H. Resis
Reg. No. 32,168
Direct Dial: (312) 463-5405

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EMSS

The EMSS provides a validated method of assessing and documenting facility operations, collecting microbial and/or particulate counts, and analyzing and trending data. This ensures that the environmental control systems are operating as intended. These trends provide valuable insight into the effectiveness of decontamination procedures, housekeeping practices, personnel training, and the potential for microbial build-up during production.

The EMSS is an "off-the-shelf," configurable means of electronically documenting, capturing, and reporting on your environmental monitoring program. CSSC will configure the database to "mirror" your environmental SOP's and facility diagrams. The EMSS is upgraded once per calendar year and released to all customers as part of their Maintenance and Upgrade program. The upgraded features are the recommendations of our current users. All users are encouraged to submit their ideas and suggestions.

The EMSS interface was developed using a Microsoft® development program, so it easy to use and intuitive. It is able to reside on hardware, and with software that already exists in almost every facility (Hardware / Software Requirements). The system's architecture was designed for a client / server installation. However, several of our customers have successfully implemented the EMSS on a Citrix® or Terminal Server®. It can be installed in virtually any network environment, is compatible with all operating systems, and is available to run with either an Oracle® or SQL Server® database.

Included with your site license for the EMSS is:

- A copy of the EMSS Software Validation Package
- System Use SOP
- Template document for performing the Installation Qualification (IQ)
- Template document for performing the Operational Qualification (OQ)
- Template document for performing the Performance Qualification (PQ)
- User Manuals

- Training Manuals

Some of the key functionality of the EMSS includes:
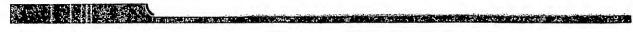
- On demand reporting that enables the user to review trends by site location and date range
- Supports a wide variety of predefined tests (i.e. particulate, microbial) as well as user defined tests (i.e. pH and chemical), including water testing
- Generates Worksheets (data sheets) and corresponding Barcode Labels to facilitate sample identification
- Custom visual layouts of facilities and test sites utilizing Microsoft Visio®
- Embedded digital photographs and video capabilities
- Automatic e-mail notification with attached historical data trend for "Alert Level" conditions
- Automatic e-mail notification with historical data trend and corrective action report generation for "Action Level" excursions
- Automatic e-mail notification with accompanying review of historical data in the event that a "flagged" organism is identified
- On-line review confirmation
- Tracks media expiration
- Tracks equipment calibration dates

Features that address the requirements of 21 CFR Part 11 includes:

- Multiple levels of security that restrict access and data modifications
- Electronic signature feature required for any additions, modifications, deletions, or reviews performed throughout the system
- Security lock-out feature
- Security time-out feature
- Password expiration
- A secure, non-modifiable, read-only / print-only audit trail automatically captures all modifications within the database

Click on the following link to download a PDF copy of CSSC's 21 CFR Part 11 Assessment Statement of the EMSS.

Click on the following link to download a PDF Presentation Binder. It includes a number of screen shots and reports from the EMSS.

Compliance Software Solutions Corporation
750 Bunker Ct., Suite 200 Vernon Hills, IL 60061
Phone: (888) 321-CSSC Email: info@csoftsol.com

[x]
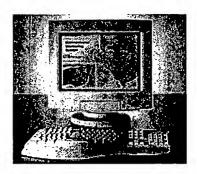
- ▣ Product Portfolio
  - Environmental
    Monitoring
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BD Diagnostic Systems, Industrial

News

Innovative Environmental Monitoring Software

Automates Data Management, Enables Regulatory Compliance

BD Diagnostic Systems, Sparks, MD, announces that it has recently launched a program built around its partnership with Compliance Software Solutions Corporation (CSSC), the developer of a unique software that automates data management for environmental monitoring. The partnership enables BD customers to enjoy the unprecedented advantages of CSSC's Environmental Monitoring Software System, known simply as EMSS. To be useful for tracking environmental contamination, data should be trended, reviewed, reported and assessed quickly. EMSS can collect, document and trend environmental monitoring data for audits and inspections, and can likewise provide critical information on the quality of the aseptic processing environment during manufacturing. This is especially beneficial for industries charged with meeting ever more stringent and changing regulatory requirements. EMSS can greatly impact businesses where environmental monitoring data is often only tracked manually via logbooks and spreadsheets – making data difficult to manage and use effectively. Compared with the management and utilization difficulties of manually tracking data in logbooks or spreadsheets, EMSS vastly improves the ability of businesses to efficiently comply with those stringent regulatory requirements.

EMSS offers BD customers a means to achieve compliance with industry regulations such as those outlined by the FDA, CFR, ISO and cGMP. EMSS automatically generates e-mails when alert or action conditions are met, or when organisms are flagged for follow-up. Use of the software can prevent the release of potentially contaminated batches if appropriate standards are not followed. Future contamination can be prevented as well because adverse trends can be detected and addressed much more quickly.

In an era when increased regulatory attention has been focused on environmental monitoring, BD is providing a meaningful, manageable and

defendable system that utilizes industry guidelines. The EMSS software package is a unique "off-the-shelf" solution to the management of environmental data, yet it can be configured to each client's facility. It can manage a full range of environmental testing at client facilities for both viable and non-viable contamination. EMSS can also support a wide range of predefined tests (e.g. particulates and microbial), all methods of water testing and can manage any user-defined tests such as pH and chemistry.

EMSS will be distributed exclusively by BD. It completes the BD breadth-of-line for environmental monitoring applications– working as an adjunct to BD BBL™ Sterile Pack Prepared Plated Media, BD Sterile Pack Swabs, BD Sterile Pack Bottles and air monitoring systems that utilize BD media. Future value-added software modules are planned for EMSS, specifically a fully automated interface with the BD Phoenix™ Microbiology System. For more information about EMSS, please call 1-800-638-8663, or contact your BD Diagnostic Systems representative.

CSSC and EMSS are trademarks of Compliance Software Solutions Corporation. BD, BBL and Phoenix are trademarks of Becton, Dickinson and Company. ©2003 BD January 2003

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BD Catapult

Propelling applications development
in the areas of Biopharm Production,
QA/QC & Environmental Monitoring

In This Issue

BD

Implementation of an Automated System for Environmental Monitoring

Jeanne E. Moldenhauer
Vectech Pharmaceutical Consultants, Inc.
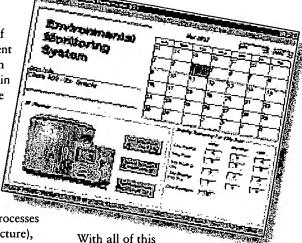
Background-Regulatory Expectations

In September 2002, the Food and Drug Administration (FDA) released a Concept Paper, "Sterile Drug Products Produced By Aseptic Processing Draft." This paper provides an indication of FDA's thinking on aseptic processing and provided an opportunity for industry comment prior to issuance of the revised guidance document on aseptic processing. Within this paper, FDA states that "in aseptic processing, one of the most important laboratory controls is the establishment of an environmental monitoring program." Environmental monitoring is also applicable to other types of processing (e.g., terminal sterilization processes and non-sterile drug manufacture), with aseptic processing being the most stringent application of these monitoring programs. The intent of these programs is to identify potential routes of product contamination and take appropriate corrective actions prior to contamination occurring. The paper also discusses many expectations for an environmental monitoring program.

In addition to the release of the "Concept Paper," there has been an increased interest in environmental monitoring by regulators worldwide. Numerous adverse findings reports have been issued in recent years, with environmental monitoring one of the most frequently identified deficiencies.

With all of this regulatory focus on environmental monitoring, it is important to have a meaningful, manageable and defendable program that will withstand the rigors of inspection by regulatory bodies. A significant problem with the design of this type of system is that a large volume of data is generated. The data is only useful if it can be trended,

Implementation of an Automated System for Environmental Monitoring

reviewed, reported and assessed in a timely manner. Finding out during a regulatory inspection that the environmental monitoring data exhibits a trend is not useful. It is important to know that a trend is occurring when it happens. Manual systems for data tracking and trending have inherent time delays in assessing the data. The time delay increases with the quantity of data generated. The "Concept Paper" defines specific expectations for trending of data (e.g., "data generated by location, lot, room, operator, or other search parameters") and specialized reports, like tracking the locations of an atypical isolate throughout the facility. Figure 1 provides some examples of the trending reports available from the Environmental Monitoring Software System (EMSS)

Figure 1 - Example of EMSS Trending Report

of Compliance Software Solutions Corporation. The reports generated by this system have been designed to meet the regulatory requirements for environmental monitoring. These expectations almost necessitate implementation and use of an automated system.

In considering automation of an environmental monitoring system, it is important to assess whether the existing monitoring system (manual) is working effectively, what requirements

must be met for the automated system, which part(s) of the system will be automated and how will automation affect the other parts of the system. A common problem in automating a system is the failure to look at the entire system when addressing what should be automated. For example, will data be both collected and reported automatically? Another problem is that you cannot effectively automate a bad system. If it doesn't work already, automating it only makes it worse than it was before.

Typical Approach to Automation

In considering a switch to an automated system for environmental monitoring, the following describes a typical approach for selection and implementation of a new system:

Evaluate/assess the existing system

• Look for compliance to applicable requirements and for the effectiveness of the system to provide a meaningful, manageable and defendable system.

• Review the documentation requirements in PDA Technical Report No. 13 (Revised) on Environmental Monitoring to ensure that all required documentation is collected. Figure 2 provides an example of a data entry screen from the EMSS system. This system has been designed to

Figure 2 - Sample of EMSS Data Entry Screen

ensure that all required documentation is maintained and generated.

• Verify the effectiveness of cleaning/disinfection systems and the accuracy of data management systems, that alert and action levels are established and appropriate, and that reports are appropriate and accurate.

• Evaluate how discrepancies and corrective actions are handled and resolved.

Evaluate opportunities for automation

• Some typical considerations here include: 21 CFR Part 11 compliance issues, opportunities to go paperless, integration of testing equipment with the automated system, etc.

• Part of this evaluation includes assessing what are the risks/costs associated with manual support operations. Automated systems come in a wide variety of applications; e.g., spreadsheets, LIMS systems, custom designed software and off-the-shelf software. There are risks and benefits associated with each type of system.

Evaluate vendors

After selecting the level of automation required and the type of system desired, one selects an appropriate vendor to support the system. Considerations for selecting vendors include:

• Technical knowledge of vendor relative to environmental monitoring

• Financial stability of vendor

• Ability of vendor to meet FDA requirements and support FDA review of the system

• Technical support available for the system

• Validation support available for the system. Software audits are often conducted to evaluate the vendor's capabilities at their site. There are very few suppliers of off-the-shelf software for environmental monitoring, including EMSS.

Select software

Defining and specifying software system requirements is a key ingredient to the selection of an appropriate system.

- When preparing these requirements, it is important that a team reviews and approves the specifications, to ensure that important characteristics are not inadvertently omitted.

- It is also important to identify which specifications are mandatory versus those that are optional. For example, when purchasing an off-the-shelf software package, one may need to accept a slightly different report format than has been used in the past. These specifications are also useful when developing the system validation requirements.

- It is important to consider the type of documentation that will support the system when specifying requirements; e.g., is a user's manual required, are sample validation protocols included, etc. Figure 3 includes a partial listing of the types of documentation provided with the EMSS system.

Figure 3
List of EMSS Documentation

User Manual
License Agreements
System Use SOP
Training Manuals
Validation Package
Validation Templates
(IQ, OQ, and PQ)

Install the software

- The computers and networks to be used with the selected system should be validated prior to installation of the software. Some companies choose to install concurrently, but this should be controlled. For example, lack of network validation for a networked monitoring system can lead to aberrations or problems at a later time.

- The system should be subjected to commissioning, debugging and "engineering" type studies to ensure that problems are minimized prior to initiating formal validation studies.

- One may also include some basic training for operators at this time.

- Many software systems also require establishment of facility drawings, parameter tables, etc., prior to validation testing.

Validate the software

Development of validation requirements should be well thought out.

- Vendors may provide validation protocols, but it is the end-user's responsibility to determine whether any other features or system integrations should be added to the testing protocol.

- One should also consider how the system will be re-qualified.

- It can be useful to establish standard data files that allow for easy repetition of data entry or reporting to minimize subsequent validation requirements; e.g., what testing will be required to replace computer boards, operating systems, etc.

- Typically, an Installation Qualification, Operational Qualification and Performance Qualification are performed. Figure 4 includes an index of a typical validation protocol for EMSS.

Implement the system

Following the validation, the system is implemented for production use.

On-going Evaluation and Maintenance

- The system should be evaluated periodically to ensure that it is still operating as designed and expected.

- Maintenance activities should also be performed and documented.

Obsolescence

At some point in time, all systems are obsoleted. Plans should be established for how these activities will be controlled and documented.

EMSS has been designed to meet the requirements for environmental monitoring systems. Figures from EMSS have been provided courtesy of Compliance Software Solutions Corporation. Additional screen shots from the EMSS system are included, to provide guidance on how this type of system can be controlled and documented.

BD Diagnostic Systems is an exclusive distributor for EMSS in North America. For further Information regarding EMSS, contact your local BD Sales Representative or fill out and return the request for information card included with this newsletter.

Figure 4
Index of CSSC Validation
Package for EMSS

Validation Report
Validation Protocol
Validation Management Plan
Requirements
Design
Process Flow Diagrams
Program Interface
Implementation / Coding
Traceability Matrix
Integration Testing
Integration Testing Attachment
Installation Testing
Boundary Testing
Boundary Testing Attachment
Error Testing
Error Testing Attachment

Jeanne Moldenhauer is a senior quality assurance/regulatory/affairs professional at Vectech Pharmaceutical Consultants, located in Farmington, Michigan. She has an extensive background in the development and management of a variety of sterilization and validation processes in the healthcare industry. She has a proven track record of successful NDA, SNDA, AADA and DMF submissions to the US Food and Drug Administration (FDA), with special expertise in the rehabilitation of companies with negative FDA findings, restoring them to compliance. Additionally, she has substantial experience in assessing and validating laboratory and production facilities in need of solutions for regulatory purposes.

COMPLIANCE SOFTWARE SOLUTIONS CORP.

750 Bunker Court • Suite 200 • Vernon Hills, IL 60061 • Tel: (847) 362-6427 • Fax: (847) 362-5019 • www.csoftsol.com

21 CFR Part 11 Compliance Assessment

Compliance Software Solutions Corporation (CSSC) has developed the Environmental Monitoring Software System (EMSS©), Version 2.2.1 to comply with the requirements defined in the FDA's 21 CFR Part 11 for Electronic Documents. The EMSS is a closed system designed to ensure accuracy, reliability, and consistently intended performance. As established in the regulation, EMSS incorporates the following:

Requirement	EMSS Assessment
Validation	CSSC offers a software validation package for the system. It includes documentation of the implementation and coding, traceability analysis, integration testing, installation testing, boundary testing, and Y2K testing.
Audit Trails	The independent and non-modifiable Audit function provides for secure, computer-generated date and time stamp of record changes and key operator entries and activities. Actions that review, create, modify or delete records are retained for viewing and / or printing. Reports can be generated for each facility by date range and specific table (audit record).
System Security	System access is limited to authorized and qualified users as established in the Security database. There are five levels of security in the EMSS, each providing the appropriate and necessary access to the required functions of Administrators, Managers, and QA / QC Users. A No Access level allows for an individual's name to be included in a drop down menu without affording that user login capability. Additionally, a separate Read-only access application is available for generating reports. The EMSS has a log out security feature, which is automatically activated once the pre-set period of time (3 – 30 minutes in one minute increments) has been met. This ensures that should a workstation be left unattended, an unauthorized individual cannot access the application.

CSSC-027

Requirement	EMSS Assessment
Password Maintenance	The EMSS provides for initial and periodic testing, as well as a user defined password expiration interval. Password expiration dates are defined and set by the Administrator (from 10 – 90 days in 5 day increments). Only the Administrator has access to Security Maintenance. Once a password expires, it can never be reused. Passwords can be alpha numeric, and must be 6 to 8 characters.
Record Retention, Protection, Retrievability, and Reproducibility	The EMSS has been designed and tested to accurately retrieve and generate all reports and database records. All electronically stored records are validated to be able to be accurately generated, retained, protected, and readily retrieved in both "human readable and electronic form" throughout the retention period. A validated archive and unarchive feature further adds to the record retention and reporting capability.
Operational Checks	Where necessary, the appropriate operational checks have been put in place to enforce step and event sequencing. The system will only allow events to be performed in the appropriate sequence. It is not possible to perform certain steps before others are complete.
Authority Checks	Only authorized personnel have access to the application, and the ability to use the system. User Maintenance / Security level access is set by the system Administrator. Each level of security has unique, restricted access to the system. The EMSS has built-in security protection that does not allow a user to make more than five attempts to log into the system. After the third unsuccessful attempt to login, the user is "locked out" of the EMSS and only the system Administrator can reactivate the user.
Device Checks	Only terminals with the EMSS installed can make data modifications / entries. This ensures the validity of the source of the data input and / or operational instruction.

Requirement	EMSS Assessment
Documentation Controls	A single copy of all system documentation is provided with the site license.
Electronic Signature Security	Only those users established in the security database that have been granted access to the EMSS can login. Attempting to enter an incorrect password three times will lock the user ID out of the system. Only the Administrator will then be able to unlock that user ID.
Password Security	Controls ensure the security, integrity, and uniqueness of the identification and password combination used for login and electronic signature. Passwords must be between 6 and 8 characters. Each password is unique. Two users cannot have the same password. Passwords are always displayed as asterisks.
Electronic Signature Assignment	Each user's unique electronic signature cannot be reused or reassigned to another user. Each user name and password is unique. Once a password expires it can never be reused again by anyone.
Electronic Signatures Not Based Upon Biometrics	Both a user name and password are required for initial login. Both are required on subsequent logins when security logoff has occurred due to inactivity in the EMSS. In order to perform reviews, additions, deletions, or modifications to any records, the authorized user is required to authenticate their identity by signing into the function and re-entering his or her password. The activity performed is then captured in the audit trail, and a full manifestation of that individual's name will appear in the audit record.
Electronic Signature With Biometric Links	The system is designed to preclude use by anyone except a genuine user. If an individual is not established in the User Maintenance database there is no ability to access the EMSS.

Requirement	EMSS Assessment
Name Display	The printed name of the individual who signs a record electronically is always clearly displayed. His or her user name will appear on relevant documents and reports generated by the system. The user ID of the individual logged into the EMSS is displayed on the lower task bar of the application window.
Signature Purpose	The meaning of each electronic signature, as defined by the individual organization, must be coupled with the appropriate procedures and training.
Signature Binding	Electronic signatures cannot be cut, or copied and pasted, or transferred by any means. The EMSS does not allow user names to be "auto-filled" into fields. Where required, those names established in the User Maintenance database can be entered in fields by means of the drop down menu.

EMS

Compliance Software Solutions Corp.

Environmental Monitoring Software System©

Compliance Software Solutions Corp.
750 Bunker Court
Suite 200
Vernon Hills, Illinois 60061
Phone (847) 362-6427
Toll Free (888) 321-2772
Fax (847) 362-5019
www.csoftsol.com

Criteria for an Effective Environmental Monitoring Program*

The EMSS©

- Date and Time of Test ☑
- Test Method/Procedure Reference ☑
- Activity Level at Site During ☑
- Equipment Identification ☑
- Location ☑
- Area Classification ☑
- Schematics of Area Showing Sample Site Locations ☑
- Sample Site (Critical and Non-Critical) ☑
- Test Results ☑
- Evaluator of Results ☑
- Date Results Read ☑
- Alert and/or Action Level ☑
- Temperature and Time of Incubation ☑
- Control Test Results ☑
- Certification, Validation, and Expiration Date of Media Used ☑
- Characterization of Contaminants ☑
- Name of Reviewer ☑
- Reporting of Data ☑
- Review of Historical Data ☑
- Change Control System ☑
- Calibration Date on Instrumentation ☑
- Methodology, Analysis Used to Specify Action/Alert Level ☑
- System for Documenting Investigative/Corrective Action ☑
  1. Description of Deficiency
  2. Possible Cause(s) of Problem
  3. Identification of Person Responsible for Relevant Corrective Action
  4. Description of Action Steps and Their Schedule for Implementation
  5. Evaluation of Effectiveness of Action Steps

* PDA Technical Report No. 13 - Fundamentals of an Environmental Monitoring Program

EMS

Environmental Monitoring

Software System©
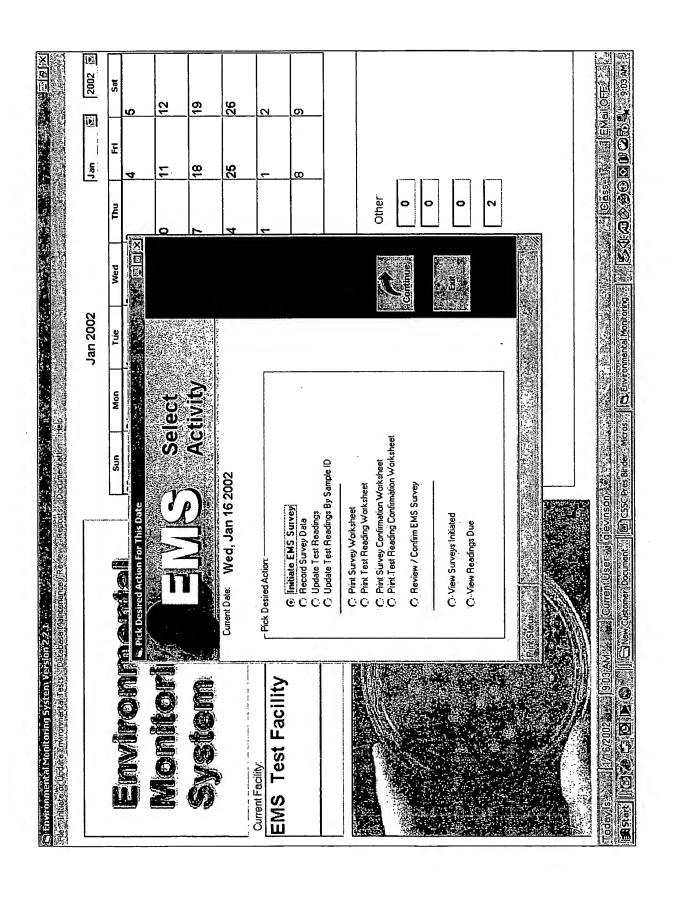
Compliance Software Solutions Corporation (CSSC)

The main menu is used to access all functions of the Environmental Monitoring Software System (EMSS). It displays current status of all test activity. The main menu includes a summary table for all relevant actions for the date selected on the calendar, including information regarding tests initiated and read on that date, test readings due on that date, and test readings past due in the categories of viable tests, non-viable tests, and other tests (i.e. water testing). It also displays the number of open testing deviations currently in need of resolution.

The drop-down menus at the top of the screen provide access to the initiate, update, and maintenance functions, along with documentation, CSSC Internet access and reporting functions. The user may initiate or update an environmental survey, and document a deviation and its investigation. The main menu also permits the user to perform maintenance on the databases outlining the facilities, rooms, test types, test sites, test groups and group assignments, and site codes and descriptions. All the reporting functions are accessed by selecting *Reports* from the upper task bar. Lastly, all support documentation including the System Use SOP for the EMSS, and the IQ, OQ, and PQ document templates are accessed by selecting *Documentation*.

Environmental Monitoring System
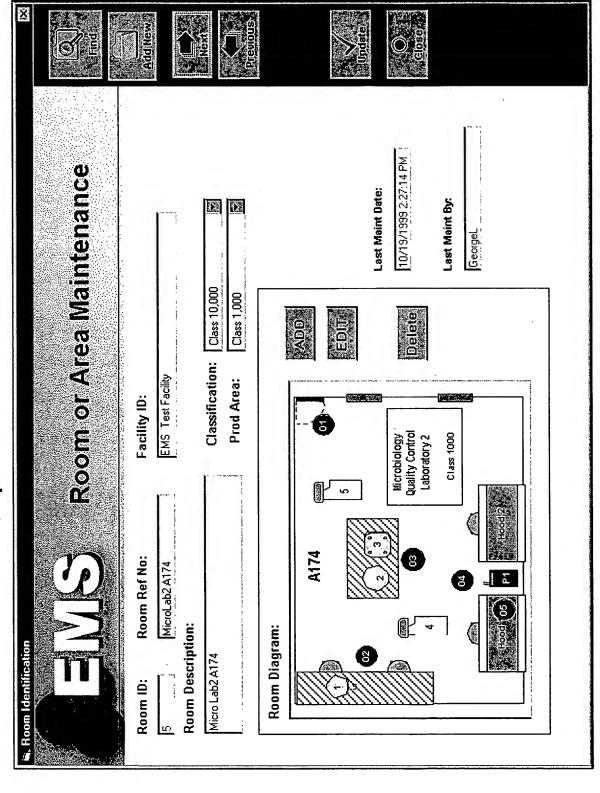
File : Initiate or Update Environmental Tests : Database Maintenance / Review : Reports : Documentation : Help

Environmental Monitoring System

Current Facility:

EMS Test Facility

Jan 2002

Jan		2002

Sun	Mon	Tue	Wed	Thu	Fri	Sat
30	31	1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31	1	2
3	4	5	6	7	8	9

Activity Summary For This Date:

	Viable	Nonviable	Other
Tests Initiated:	0	0	0
Tests Read:	0	0	0
Test Readings Due:	0	0	0
Test Readings Past Due:	15	12	2
Open Deviations:	5		

When selecting a date on the calendar, the operator can access other EMSS activities. Double-clicking on the highlighted date brings up the Select Activity form, which presents the user with several options. These include initiating a new survey, updating survey data, updating current test readings, printing survey and test reading worksheets, and an ability to view any and all initiated surveys and readings due. Many of these same functions can be accessed using the *Initiate or Update Environmental Tests* drop-down menu.

Environmental Monitoring System

EMS

Current Facility:
EMS Test Facility

Select Activity

Current Date: Wed, Jan 16 2002

Pick Desired Action:

- ⊙ Initiate EMS Survey
- ○ Record Survey Data
- ○ Update Test Readings
- ○ Update Test Readings By Sample ID

- ○ Print Survey Worksheet
- ○ Print Test Reading Worksheet
- ○ Print Survey Confirmation Worksheet
- ○ Print Test Reading Confirmation Worksheet

- ○ Review / Confirm EMS Survey

- ○ View Surveys Initiated
- ○ View Readings Due

Print Status

Continue

Exit

Jan 2002

Jan | 2002

Sun	Mon	Tue	Wed	Thu	Fri	Sat
				0	4	5
				7	11	12
				4	18	19
				1	25	26
					1	2
					8	9

Pick Desired Action For This Date

Other

| 0 |
| 0 |
| 0 |
| 2 |

The Facility Maintenance, and Room or Area Maintenance screens are accessed through the *Database Maintenance* drop-down menu and selecting *Facility or Rooms / Areas*, respectively. Compliance Software Solutions has chosen Visio® to create all the facility and room / area diagrams in the EMSS. A single user site license for Visio® Standard is provided with the EMSS site license.

Rooms or areas are defined for each facility created in the system. Areas could be used to define general facility parameters or for facility water systems, HVAC systems, etc. The user can perform maintenance on the room / area utilizing the Room or Area Maintenance screen. The room / area information which can be configured by the user includes the room description, room reference number, room and production area classification, and the room diagram itself. Below is a representative screen of a room / area created in Visio®. Note that the system allows for two classifications to be set-up within the same room / area (i.e. Class 100 and Class 10,000). A text table within the EMSS enables the user to personalize their classification drop down menu (i.e. U.S. standards or European standards).

Environmental Monitoring System
Graphical User Interface

Room or Area Maintenance

Room Identification

Find | AddNew | Next | Previous | Update | Close

Room ID: 5

Room Ref No: MicroLab2 A174

Facility ID: EMS Test Facility

Room Description: Micro Lab2 A174

Classification: Class 10,000

Prod Area: Class 1,000

Last Maint Date: 10/19/1999 2:27:14 PM

Last Maint By: GeorgeL

Room Diagram:

ADD | EDIT | Delete

A174

Microbiology Quality Control Laboratory 2

Class 1000

Hood 2

Hood 03

P1

01 02 03 04 05

1 2 3 4 5

Generating or modifying the graphical representations of the facilities and rooms / areas in the system is accomplished by "clicking" on the ADD or EDIT buttons that appear on the maintenance screens. The graphics generated not only document objects within the room, they can also be used to document test sites. These diagrams are displayed on the worksheets, as well as on many of the reports. When the ADD or EDIT buttons are clicked, the current facility, or room diagram opens in Visio®. CSSC has created a custom stencil of recognizable icons to facilitate the creation or modification of the facility and room diagrams. These icons can be easily "clicked" and "dragged" into the facility or room diagram, in order to identify and specify where a particular test is to be performed, or a structure is located.

The templates support a wide variety of predefined tests (i.e. particulate, microbial), as well as user-defined tests (i.e. pH, pressure, chemical).

Environmental Monitoring System
Graphical User Interface

The system has the ability to automatically assign identification numbers to survey test samples. To activate this feature, the operator selects the Auto Assign Survey ID checkbox.

The system also has the capability to require identification for any media lots and equipment utilized in the testing. To activate these features, the operator selects the Require Media Lots / Require Equipment ID checkboxes.

The user may update the facility name, and reference the frequency of a facility's review (re-validation) utilizing the Facility Name and Review Frequency fields respectively.

The periodic review status may be updated utilizing the checkbox on the screen. A facility can be activated by checking the Active checkbox. Inactivating a facility (such as one set up to perform a validation or specific testing) prevents inadvertently changing facilities, and data entry into a facility other than the current production environment.

As with the Room / Area Maintenance, the EMSS assigns a unique ID to every Facility that is created in the database. This ensures that no duplications exist within the program.

Environmental Monitoring System -Facility

EMS Facility Maintenance

Facility ID: [2] Facility Status: ☑ Active

Facility Name: [EMS Test Facility]

Periodic Review: ☑

Review Freq: [Annually ▼]

Last Review: [5/1/1999]

Next Review: ☑ [4 /30/2000 ▼]

☑ Auto Assign Sample ID
☑ Require Media Lot
☑ Require Equipment ID's

Facility Diagram:

ADD
EDIT
Delete
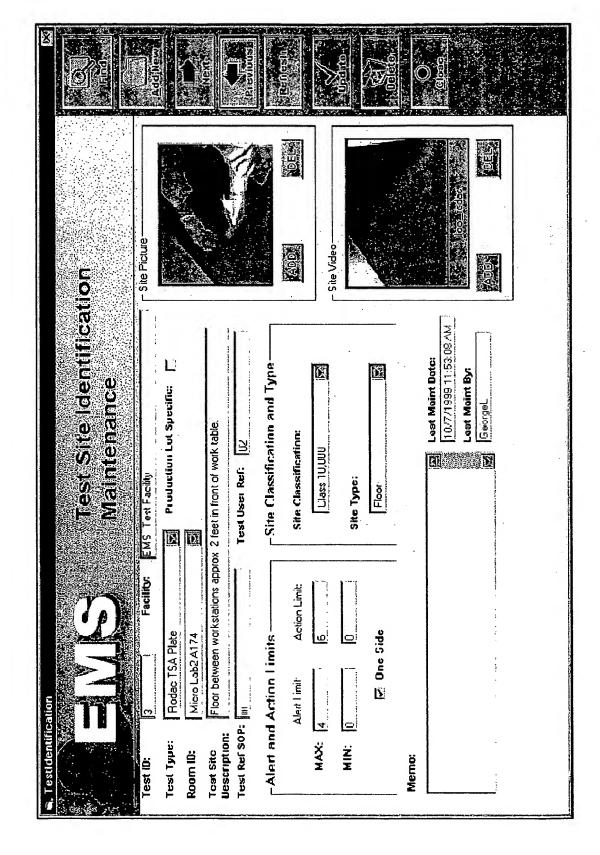
Last Maint Date: [5/24/2000 11:11:05 AM]

Last Maint By: [georgel]

Find
Next
Previous
AddNew
Update
Close

Audit Function   Audit Message

The user can review or perform maintenance on the test site information utilizing the Test Site Maintenance screen. The test identification information which can be configured when a site is identified includes the test type, room identification, site type, site classification, test site description, reference SOP, user reference number, the alert and action limits, and any comments associated with that site.

The Test Identification Maintenance screen may be accessed by utilizing the *Database Maintenance* drop-down menu and selecting *Test Site Identification.*

To enhance comprehension of the test procedure a site picture and / or site video can be embedded in the software and viewed on this screen. The video clip not only provides a visual representation of the referenced procedure, it also facilitates identification of the site and potentially minimizes operator error.

Environmental Monitoring System
Graphical User Interface

Both the Test Group Maintenance and Group Assignments functions can be accessed by utilizing the *Database Maintenance* drop-down menu and selecting *Test Groups or Group Assignments*, respectively.

The user can establish groups based on the frequency with which specific tests are performed. Once the groups are set, and the rooms / areas and sites within those rooms are defined, tests can be assigned to a desired group (frequency). If all the test sites in a specific room are part of a specific group, they can all be selected by using the *Select All* button. The *Remove All* button will uncheck all those boxes that are selected.

Test sites are selected individually by clicking on the checkbox adjacent to each location description for the current room.

EMS — Test Group Maintenance

Find · Add New · Next · Previous · Update · Delete

Group ID: 2   ☐ Inactive Status

Group Description: Weekly Tests

Frequency: Weekly   ☐ Lot Specific

Num To Pick:

☐ Random Pick

Last Maint Date: 5/31/2001 11:51:31 AM

Last Maint By: georgel

Audit Functions · Audit Messal

EMS — Group Assignments

Select the Test Group
Weekly Tests

Select Room or Area
- Micro Lab1
- Micro Lab2 A174
- Micro Sterility Suite
- Micro Gowning Area
- Production Room 209 Lyophilization
- Production Room 207 Tablet Milling
- Production Room 208 Packaging
- Production Room 205 Raw Material Sto
- Production Room 206 Personnel Prep A
- Production Room 100 Hallway
- Production Room 101 Gowning Area
- Production Room 102 Bottle Storage
- Production Room 103 Bottling
- Production Room 104 Capping.
- Water System
- New Room Name 1
- New Room Name 2

Check Tests In Group

TestID	Description	Test Number
13	Floor site in doorway - room entrance.	F1
14	Floor site in front of laminar flow hood.	F2
15	Floor site in doorway - to sterility suite.	F3
16	Floor site in front of sinks.	F4
17	Floor site in center of room.	F5
18	Site on work surface of laminar flow hood.	E1
19	Swab sample within sink 1.	S1
20	Swab sample within sink 2.	S2
21	Fallout plate within laminar flow hood.	1
22	Touch plate taken on work surface.	ZZ1
23	Airborne contamination count taken in center of room.	1

Select All · Remove All · Update · Exit

To initiate a test by room / area or test ID, the user selects *Initiate Test → By Room / Area or Test ID* from the *Initiate or Update Environmental Tests* drop-down menu. This action will bring up the Initiate Test By Room or Test ID screen, which allows the user to initiate an environmental survey according to its room location or its individual test ID. This is typically used for sites to be tested that are not part of a specific group (e.g. retesting a site as a result of an excursion, or an infrequently tested site). Group Tests can be initiated in a similar manner off the same task bar function, as well as by double clicking on the highlighted date on the main menu and choosing the *Initiate EMS Survey* radio button and clicking *Continue*.

After the test(s) has been selected, the user is prompted for personnel identification, product code, lot number, and shift information on Survey screen. The user may then direct the EMSS to generate the documentation required to perform the selected test(s) by clicking on the *Initiate* button. The system can be set to display a preview of the Survey Worksheet. The user may print the generated worksheets by clicking on the print button. The printed worksheets are used by the Technician to record all pertinent sampling information.

Environmental Monitoring System

Survey Worksheet

Report Date: 6/2/2000

Facility: EMS Test Facility
Group   Daily Tests

Survey Control No.   1074
Survey Date: 6/2/2000
Survey Shift: 1

Room ID: 4

RefNo   A174

Room Description
Micro Lab 1

Microbiology
Quality Control
Laboratory 1
Class 10,000
G124

To
Sterility
Suite

Activity Level

| Static |
| Operations |

Fallout Plate

Test ID:	Test Ref	Site Type Test Description	Sample Date/Time Sample By Sample ID	On Test Date/Time Equipment ID/ On Test By Media Lot
21	1	Critical Surface		Equip
		Fallout plate within laminar flow hood.	+ S08093A	Media

Non Viable Particulate

Test ID:	Test Ref	Site Type Test Description	Sample Date/Time Sample By Sample ID	On Test Date/Time Equipment ID/ On Test By Reading
24	P1	Counter		Equip
		Particulate count taken in room center.	+ S08096A	Read

RCS Air Sample

Test ID:	Test Ref	Site Type Test Description	Sample Date/Time Sample By Sample ID	On Test Date/Time Equipment ID/ On Test By Media Lot

The user can also elect to have bar code labels printed for the tests outlined on the Survey Worksheet. Bar codes provide an effective and efficient means of identifying samples. The bar code labels that are generated by the EMSS are typically printed on a laser printer on a standard self-stick Avery® label stock. A wedge or wand type bar code reader is used to scan these labels when plates are scheduled to be read from the lab.

Survey #	Room	Test Type	Test ID	Location	Barcode ID	Date / Time
1074	6	Water pH	1432	WFI-000-1	+S08079A	Date: 6/2/200(Time
1074	74	ster Endotoxin ELU	1433	D1LAL1	+S08080A	Date: 6/2/200(Time
1074	74	ster Endotoxin ELU	1435	D3LAL3	+S08081A	Date: 6/2/200(Time
1074	74	Water pH	1436	D1PH1	+S08082A	Date: 6/2/200(Time
1074	74	Water pH	1438	D3PH3	+S08083A	Date: 6/2/200(Time
1074	74	Water Conductivity	1443	WFI=003-02	+S08084A	Date: 6/2/200(Time
1074	4	Roac TSA Plate	17	F5	+S08089A	Date: 6/2/200(Time
1074	4	Roac TSA Plate	18	E1	+S08090A	Date: 6/2/200(Time
1074	4	Surface Swab	19	S1	+S08091A	Date: 6/2/200(Time
1074	7	Surface Swab	20	S2	+S08092A	Date: 6/2/200(Time
1074	7	Surface Swab	32	S1	+S08066A	Date: 6/2/200(Time
1074	7	Surface Swab	33	S2	+S08067A	Date: 6/2/200(Time
1074	6	Roac TSA Plate	38	F1	+S08072A	Date: 6/2/200(Time
1074	6	Roac TSA Plate	39	F2	+S08073A	Date: 6/2/200(Time
1074	6	Roac TSA Plate	40	F3	+S08074A	Date: 6/2/200(Time
1074	6	Roac TSA Plate	41	E1	+S08075A	Date: 6/2/200(Time
1074	6	Touch Plate	42	TP1	+S08076A	Date: 6/2/200(Time
1074	6	STA Plate	44	1	+S08077A	Date: 6/2/200(Time

By

In order to select the survey to be updated from the worksheets, the user selects the *Record Survey Data* radio button from the *Select Activity* menu accessed by double clicking the highlighted date on the calendar.

The user can view All OPEN surveys or All Surveys for a given date or date range. Highlighting the desired Survey # and clicking *Select*, will open that survey update form.

EMS

EMS Survey Data Update

Select Survey To Record Sampling Data.

Survey Date:

April 2000						
Sun	Mon	Tue	Wed	Thu	Fri	Sat
26	27	28	29	30	31	1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	1	2	3	4	5	6

Today: 6/2/2000

All Surveys

Surveys Initiated

Survey #	Survey Description	Shift	Open Surveys	Open Read	Total Tests	Status
1070	Daily Tests	1	41	42	43	Inc Survey
1071	Daily Tests	1	40	41	41	Inc Survey

SELECT

Exit

Once a particular survey is selected from the EMS Survey Data Update screen, the Survey Data Entry / Update screen opens, and displays a drop down menu for each of the rooms included on the survey, as well as a drop down for each test type in that room on that survey (i.e. Rodac TSA Plates, Non-Viable Particulate, etc.). Selecting from these two drop down menus will display all the survey data fields for that test type and room in the table below.

The user is prompted in the *Status* column to enter the required data in the appropriate field for that specific row (e.g. Sample Date/Time, Sample By, On Test Date/Time, etc.). Sample ID's are assigned a unique number if this feature has been selected for the current facility.
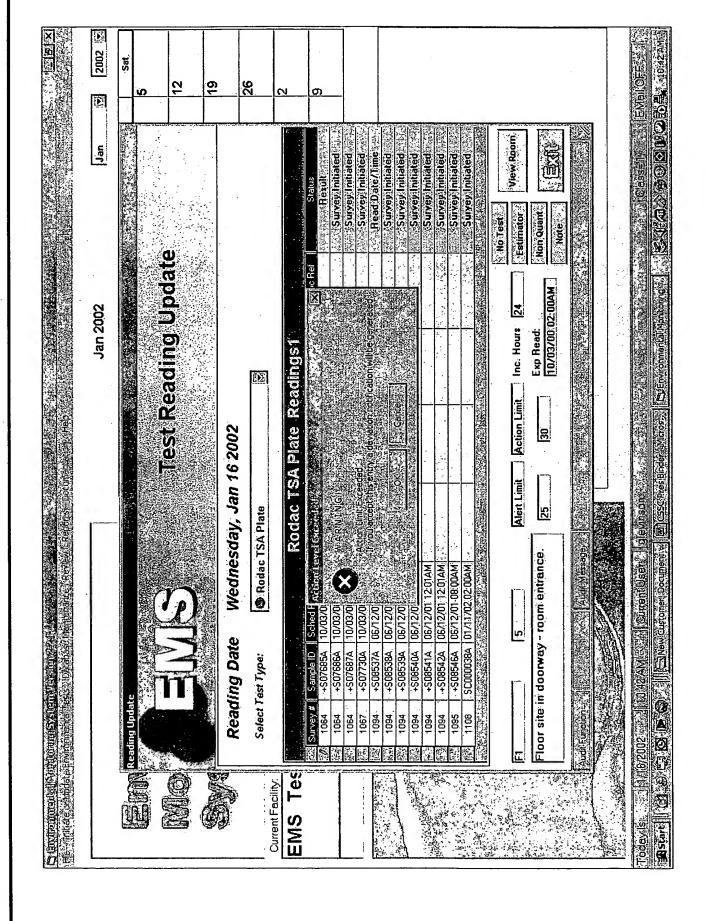
The *Media Lot number* (if applicable), and the *Equipment ID* fields are selected utilizing the drop-down menus in the individual fields. Only those media lots or equipment "flagged" as being within the expiration date or calibration date in the Media Growth Promotion Test and Equipment Calibration Data tables will be displayed on the drop down. The maintenance for these fields is accessed from the main screen database / maintenance drop down menu, and selecting *Media Growth Promotion Test* or *Equipment Calibration Data*. Equipment ID's and Media Lots can be defaulted to a single selection by utilizing the *Edit Equip ID's* or *Edit Media Lots* buttons, respectively.

A "No Test" may be recorded for a particular sample by clicking on the *No Test* button on the screen. If the survey result is a *No Test*, the system will prompt the user for an explanation via the *No Test Confirmation* screen. The individual room in which you are updating data can be viewed at any time by clicking on the *View Room* button. Additionally, *Notes* may be added to the record.

EMS

Survey Data Update

Survey No.
1108

Group Desc:
Daily Tests

Select Room/Area: Micro Lab 1 rr

Rooms In Survey: 5

Select Test Type: ● Rodac TSA Plate

Room Activity Level
● Static
○ Dynamic

Edit Equip ID's

Edit Media L ts

Rodac TSA Plate Viable2

Test ID Ref	Sample Date	Sample By	Sample ID	On Test Date	On Test By	Media Lot	Equipment ID
							Status
F5	01/10/02 12:00AM	JRadigan	SC000039A	01/10/02 12:00AM			
							Sample Date/Time
E1	01/10/02 12:00AM	JRadigan	SC000040A	01/10/02 12:00AM			
							Not Started
F2	01/10/02 12:00AM	JRadigan	SC000026A	01/10/02 12:00AM			
							Not Started
F4	01/10/02 12:00AM	JRadigan	SC000015A	01/10/02 12:00AM			
							Not Started
F1	01/10/02 12:00AM	JRadigan	SC000014A	01/10/02 12:00AM			
							Not Started

Alert Limit: 25

Action Limit: 30

Inc. Hours: 24

Exp Read: 01/11/02 12:00AM

No Test

View Ro m

EXIT

Note

Test ID Ref: F5

Test ID: 17

Fl or it in center of room.

The test reading values may be entered onto the *Test Reading Update* screen. If the value is calculated utilizing the Estimator function the displayed value is noted with a block letter "E". If the test result is a Non Quantifiable (or TNTC) condition, this may be entered into the system by clicking on the *Non Quant* button. The system will prompt the user for confirmation of the non-quantifiable condition, and create a deviation record for that test survey. A *No Test* may be entered for a sample by clicking on the *No Test* button. If the survey results in a *No Test* condition, the system will prompt the user for confirmation using the *No Test Confirmation* screen.

As data is entered, if the alert or action level (displayed at the bottom of the screen) is exceeded for a test, a message is displayed for the operator to acknowledge. If an action limit or alert limit is exceeded, the Action Level Exceeded or Alert Level Exceeded message boxes are displayed, respectively. Each requires confirmation of the excursion condition. The user may confirm the action / alert limit was exceeded for the survey by clicking the *OK* button; the entered number is then written to the EMSS database. If the user selects the *Cancel* button, the active field in the *Test Reading Update* table is "erased" and must be entered again. If an action limit is exceeded and confirmed by the operator, a deviation record is automatically generated for subsequent processing and corrective action. A deviation can also be manually generated when an alert limit is exceeded. The EMSS automatically generates and sends an e-mail notification message to the appropriate company personnel notifying them of all aberrant conditions. The EMSS will automatically generate a historical profile for the aberrant site and attaches it to the e-mail notification.

If an alert level is exceeded and confirmed by the operator the entered number is then written to the EMSS database. The EMSS also automatically generates and sends an e-mail "adverse trend" message to the appropriate company personnel notifying them of the aberrant condition. A historical profile is attached to this e-mail message, as well.
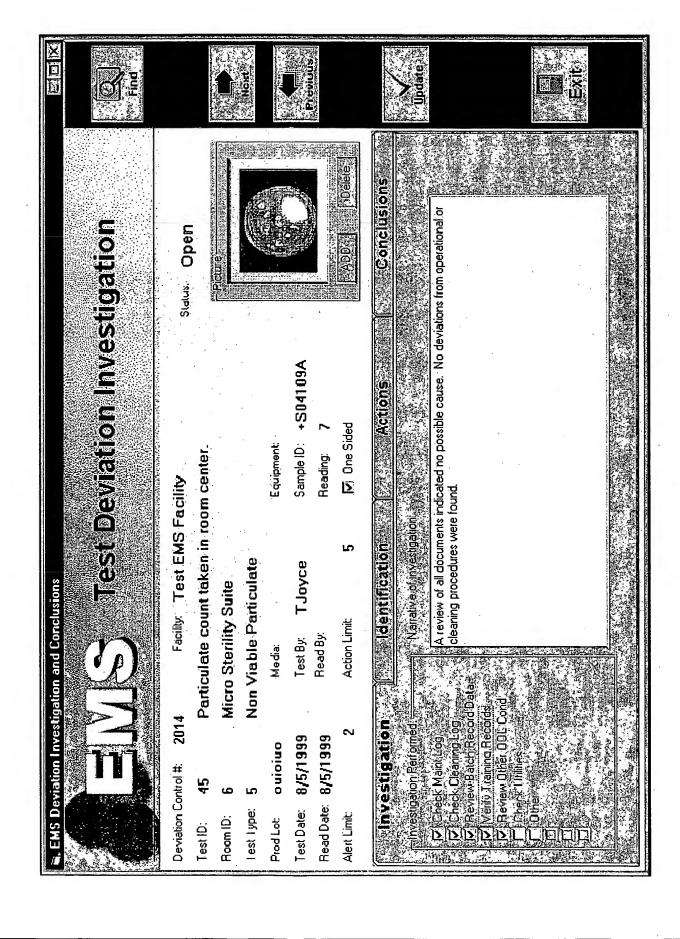
The total number of current deviations in need of resolution is displayed on the main menu screen. Deviations must be resolved using the Test Deviation Investigation form accessed from the main menu *Initiate or Update Environmental Tests*.

Environmental Monitoring System Version 2.4

File Tricate or update Environmental Tests Update User Maintenance Review Reports Documentation Help

Reading Update

EMS

Test Reading Update

Reading Date Wednesday, Jan 16 2002

Select Test Type: ◉ Rodac TSA Plate

Current Facility:

EMS Tes

Rodac TSA Plate Readings1

Survey #	Sample ID	Sched		ic Ref	Status
1064	+S07685A	10/03/0			Survey Initiated
1064	+S07686A	10/03/0			Survey Initiated
1064	+S07687A	10/03/0			Survey Initiated
1067	+S07730A	10/03/0			Read Date/Time
1094	+S08537A	06/12/0			Survey Initiated
1094	+S08538A	06/12/0			Survey Initiated
1094	+S08539A	06/12/0			Survey Initiated
1094	+S08540A	06/12/0			Survey Initiated
1094	+S08541A	06/12/01 12:01AM			Survey Initiated
1094	+S08542A	06/12/01 12:01AM			Survey Initiated
1095	+S08546A	06/12/01-08:00AM			Survey Initiated
1108	SC000038A	01/11/02 02:00AM			Survey Initiated

Action Level Exceeded

❌ **WARNING!**

Action Limit Exceeded
If you accept this entry, a deviation notification will be generated.

OK   Cancel

Alert Limit	Action Limit	Inc. Hours	No Test	View Room
25	30	24	Estimator	Exit
		Exp Read:	Non Quant.	
		10/03/00 02:00AM	Note	

F1   5

Floor site in doorway - room entrance.

Audit Function   Audit Message

New Customer Document   Current User   Eric Johnson   CSC Pres Binders Micros   Environmental Monitoring

Today is   1/16/2002   10:42 AM

EMail OFF   Class 1   10:42 AM

Start

Jan   2002

| Sat. |
| 5 |
| 12 |
| 19 |
| 26 |
| 2 |
| 9 |

The user can access the Test Deviation Investigation screen by utilizing the Initiate or Update Environmental Tests drop-down menu and selecting Update Deviation Investigation.

A deviation record is automatically generated in the event the results of the survey exceed the relevant testing limits. Following any investigation into the details of the deviation in question, the corrective actions and final conclusions are documented in order to resolve the deviation.

The Test Deviation Investigation screen contains tabs for Investigation details, Identification (morphology) details, Actions narrative, and Conclusions reached as a result of the deviation investigation.

The user can scroll through all existing deviation records by utilizing the Next / Previous buttons on the right of the Test Deviation Investigation screen. The EMSS automatically retrieves all pertinent information for the current deviation and displays this in the General tab.

The checkboxes (user created) on the left side of the Investigation tab along with the text box on the right are used to describe in detail the particulars of the investigation

The Actions tab contains a text box, which may be used to enter the description for the actions taken.

The Conclusions tab may be used to describe the final conclusions for the deviation and its resolution status using the Close checkbox. Identification of the individual resolving the deviation, as well as the date and time of its resolution, must also be specified.

EMS Test Deviation Investigation

Deviation Control #: 2014   Facility: Test EMS Facility   Status: Open

Test ID: 45   Particulate count taken in room center.

Room ID: 6   Micro Sterility Suite

Test Type: 5   Non Viable Particulate

Prod Lot: ouioiuo   Media: Equipment:

Test Date: 8/5/1999   Test By: T Joyce   Sample ID: +S04109A

Read Date: 8/5/1999   Read By: Reading: 7

Alert Limit: 2   Action Limit: 5   ☑ One Sided

Picture

[ADD] [Delete]

Investigation | Identification | Actions | Conclusions

Investigation Performed:

☑ Check Maint Log
☑ Check Cleaning Log
☑ Review Batch Record Data
☑ Verify Training Records
☑ Review Other OOL Cond
☐ Check Utilities
☐ Other

Narrative of Investigation:

A review of all documents indicated no possible cause. No deviations from operational or cleaning procedures were found.

[Find]
[Next]
[Previous]
[Update]
[Exit]

If applicable, results for Gram Stain procedures performed can be captured, along with the identification of the organism(s) genus and species on the *Identification* tab; macroscopic organism morphology characteristics may also be recorded. The organism morphology drop down menus on the Identification tab can be created by the user from the *Text Support Tables* accessed from the *Database Maintenance / Review* drop down.

EMS Deviation Investigation and Conclusions

EMS

Test Deviation Investigation

Deviation Control #:	2014	Facility:	Test EMS Facility	Status:	Open

Test ID: 45   Particulate count taken in room center.

Room ID: 6   Micro Sterility Suite

Test Type: 5   Non Viable Particulate

Prod Lot: ouioiuo   Media: Equipment:

Test Date: 8/5/1999   Test By: TJoyce   Sample ID: +S04109A

Read Date: 8/5/1999   Read By: Reading: 7

Alert Limit: 2   Action Limit: 5   ☑ One Sided

Picture [Add] [Delete]

Investigation | Identification | Actions | Conclusions

Observed Morphology
Obs 1 | Obs 2 | Obs 3

Source: Vitek   Report No.: 102A45   Equipment ID: 999-A123

Media Type: TSA   Light Trans: Transparent   Elevation: Depressed   Surface Appear: Bumpy

Gram Stain: Pos   Microscopic: rod   Genus: Bacteria   Surface Texture: Layered   Margin/Edge: -N/A-

Memo:

Species: Bacillus cereus

ID Date: 9/3/1999   ID By: JRadigan

Pigmentation: Pink   Size: Small

Picture

Add Organism

[Add] [Del]

[Find] [Next] [Previous] [Update] [Exit]

The Environmental Monitoring System includes a complete reporting package for presentation, analysis, and review of all input test survey data, all relevant testing detail, and database listings information, as well as a wide variety of reports summarizing analyzed and processed surveys.

The Management Reports include a trend analysis package that can retrieve data from a selected time period for presentation and review on demand. This is useful for internal reviews, customer / client audits, regulatory inspections, etc.

EMS
Test Site Data Graphs

Room: **Micro Lab2 A174**

Test Site: **Floor in center of room.**
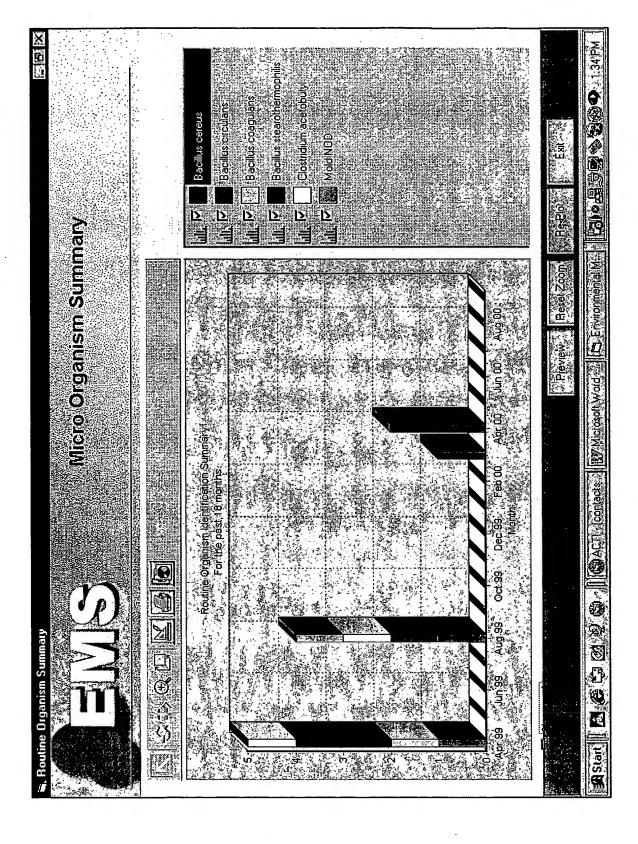
Histogram

Site Test Readings

Legend:
— Data
— Trend
— Avg
♦ MaxAlert
♦ MaxAction

Survey Results for Period

Test Date	Survey ID	Shift	Product Lot	Test By	Sample ID	Read Date
1/8/2000 6:30:04 PM	1039			TJoyce	S06904A	1/15/2000 9:26:04 PM
1/15/2000 10:30:05 PM	1040	1		GeorgeL	S06945A	1/23/2000 12:36:05 AM
1/22/2000 5:30:05 PM	1041	1		GeorgeL	S06986A	1/29/2000 8:29:05 PM
1/25/2000 11:30:05 PM	1042	1		GeorgeL	S07027A	2/2/2000 2:14:05 AM
2/5/2000 10:30:05 PM	1043	1		JRadigan	S07068A	2/13/2000 12:56:05 AM
2/10/2000 10:30:05 AM	1044	1		JTR	S07109A	2/17/2000 1:30:05 PM
2/20/2000 4:30:05 AM	1045	1		JTR	S07150A	2/27/2000 5:55:05 AM
2/23/2000 9:30:05 PM	1046	1		GeorgeL	S07191A	3/1/2000 10:34:05 PM

Print Report   Stats   Print Graphs   Exit
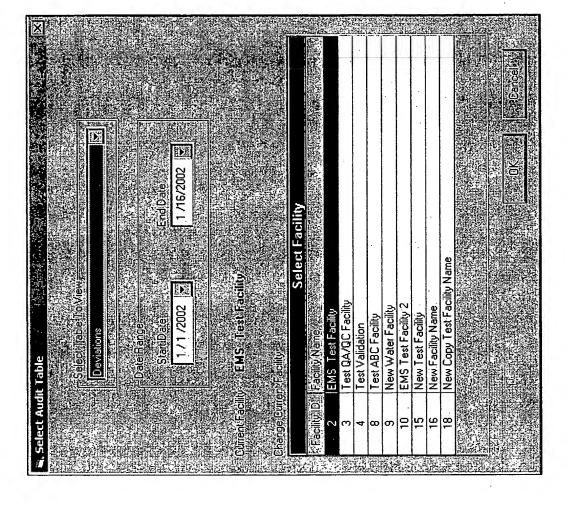
Routine organism identification data can be retrieved and displayed to reveal frequencies and trends. Organisms added to the genus / species drop down menu created by the user can be "flagged" as objectionable. When identified, the EMSS will treat this as an excursion, and generate an e-mail along with the corresponding document for the site.

The EMSS meets the electronic records and electronic signature requirements of 21CFR Part 11. Some of the EMSS features include a required logon using a valid user name and password; multiple levels of security with defined access to the application; passwords that expire and can never be reused again; lock out feature preventing unauthorized access to the program; time out feature logging off the user during a defined period of inactivity; full featured, independent, non-modifiable audit trail; and sign in required to perform additions, deletions, modifications, and reviews of all records.

The independent and non-modifiable Audit function provides for secure, computer-generated date and time stamp of record changes and key operator entries and activities. Actions that review, create, modify or delete records are retained for viewing and / or printing. Reports can be generated for each facility by date range and specific table (audit record).

Select Audit Table

Select Table To View
[Deviations ▼]

Date Range
Start Date [1/1/2002 ▼]   End Date [1/16/2002 ▼]

Current Facility : EMS Test Facility

Change Current Facility

Select Facility

Facility ID	Facility Name
2	EMS Test Facility
3	Test QA/QC Facility
4	Test Validation
8	Test ABC Facility
9	New Water Facility
10	EMS Test Facility 2
15	New Test Facility
16	New Facility Name
18	New Copy Test Facility Name

[OK]   [Cancel]

The recent annual upgrade to the EMSS included several new special processing features for establishing test types. In addition to the USP model for Water Conductivity, test results can be captured for sites requiring two readings (e.g. samples that are incubated at two temperatures and incubation times), and multiple readings (e.g. particulate samples).

The multiple readings feature enables the user to capture up to 49 (7 x 7 grid) results for a single sample, and select an average of the total.

In addition, a model was created to collect and calculate air samples, in a standardized unit of measure and volume of air. Samples can be collected in cubic meters, cubic feet, or liters and converted to a single unit of measure for reporting.

EMS

Average Calculation For Multiple Samples

Selected Sample ID: **SC000051A**

Number of Pkg Units: 7   Number of Samples/Unit: 7

	Pkg Unit 1	Pkg Unit 2	Pkg Unit 3	Pkg Unit 4	Pkg Unit 5	Pkg Unit 6	Pkg Unit 7
Sample 1							
Sample 2							
Sample 3							
Sample 4							
Sample 5							
Sample 6							
Sample 7							

Calculate   Exit

Sample Historical Reports
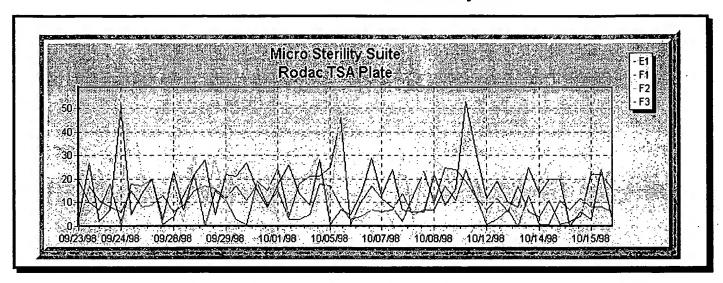
Environmental Monitoring System

Report Date: October 21, 1999

Facility **EMS T st Facility**

Room **Micro Sterility Suite**

Micro Sterility Suite
Rodac TSA Plate
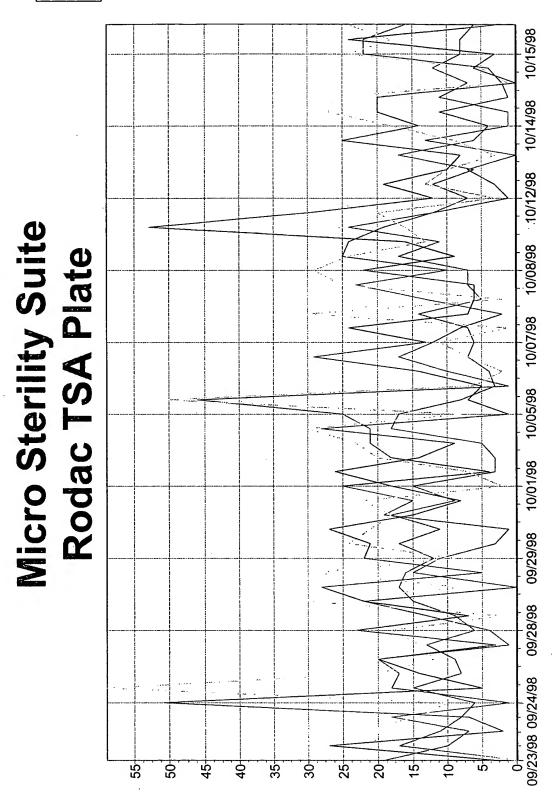
Test ID User Ref	Test Description	Test Date	Reading	Activity	TNTC	No T st
E1	**Site on work surface of laminar flow hood.**					
		9/23/98	0.00	Static	No	No
		9/23/98	17.00	Static	No	No
		9/23/98	11.00	Static	No	No
		9/24/98	8.00	Normal	No	No
		9/24/98	6.00	Static	No	No
		9/24/98	15.00	Static	No	No
		9/25/98	8.00	Static	No	No
		9/25/98	9.00	Static	No	No
		9/25/98	13.00	Static	No	No
		9/28/98	6.00	Normal	No	No
		9/28/98	9.00	Static	No	No
		9/28/98	15.00	Static	No	No
		9/29/98	17.00	Static	No	No
		9/29/98	16.00	Static	No	No
		9/29/98	12.00	Static	No	No
		9/30/98	17.00	Static	No	No
		9/30/98	11.00	Static	No	No
		9/30/98	18.00	Static	No	No
		10/1/98	100.00	Static	Yes	No
		10/1/98	9.00	Static	No	No
		10/1/98	15.00	Static	No	No
		10/2/98	3.00	Static	No	No
		10/2/98	3.00	Static	No	No
		10/2/98	5.00	Static	No	No
		10/5/98	18.00	Static	No	No

CSSC Pharmaceuticals

Environmental Monitoring System

Report Date: October 21, 1999

Facility   **EMS Test Facility**
Room   **Micro Sterility Suite**

Test ID User Ref	Test Description	Test Date	Reading	Activity	TNTC	No Test
		10/5/98	17.00	Normal	No	No
		10/5/98	8.00	Static	No	No
		10/6/98	3.00	Static	No	No
		10/6/98	4.00	Static	No	No
		10/6/98	7.00	Static	No	No
		10/7/98	6.00	Static	No	No
		10/7/98	7.00	Static	No	No
		10/7/98	14.00	Static	No	No
		10/8/98	5.00	Static	No	No
		10/8/98	7.00	Static	No	No
		10/8/98	7.00	Static	No	No
		10/9/98	17.00	Static	No	No
		10/9/98	11.00	Normal	No	No
		10/9/98	24.00	Static	No	No
		10/12/98	12.00	Static	No	No
		10/12/98	1.00	Static	No	No
		10/12/98	3.00	Static	No	No
		10/13/98	7.00	Static	No	No
		10/13/98	0.00	Static	No	No
		10/13/98	13.00	Static	No	No
		10/14/98	1.00	Static	No	No
		10/14/98	1.00	Static	No	No
		10/14/98	11.00	Static	No	No
		10/15/98	7.00	Static	No	No
		10/15/98	12.00	Static	No	No
		10/15/98	8.00	Static	No	No
		10/16/98	8.00	Static	No	No
		10/16/98	6.00	Static	No	No
		10/16/98	1.00	Static	No	No
		10/19/98	10.00	Static	No	No
		10/19/98	15.00	Static	No	No
		10/19/98	1.00	Static	No	No
		10/20/98	3.00	Static	No	No
		10/20/98	7.00	Static	No	No
		10/20/98	15.00	Static	No	No
		10/21/98	1.00	Static	No	No
		10/21/98	4.00	Static	No	No
		10/21/98	10.00	Static	No	No
		10/22/98	18.00	Static	No	No
		10/22/98	6.00	Static	No	No
		10/22/98	4.00	Static	No	No

Micro Sterility Suite
Rodac TSA Plate

Environmental Monitoring Syst m

Report Date: October 21, 1999

Facility   **EMS Test Facility**

Room   **Micro Sterility Suite**

Test ID User Ref	Test Description	Test Date	Reading	Activity	TNTC	No Test
JSmith	**Touch plate taken within laminar flow hood.**					
		9/23/98	10.00	Static	No	No
		9/23/98	16.00	Static	No	No
		9/23/98	2.00	Static	No	No
		9/24/98	1.00	Normal	No	No
		9/24/98	9.00	Static	No	No
		9/24/98	8.00	Static	No	No
		9/25/98	4.00	Static	No	No
		9/25/98	12.00	Static	No	No
		9/25/98	6.00	Static	No	No
		9/28/98	6.00	Normal	No	No
		9/28/98	4.00	Static	No	No
		9/28/98	17.00	Static	No	No
		9/29/98	14.00	Static	No	No
		9/29/98	18.00	Static	No	No
		9/29/98	17.00	Static	No	No
		9/30/98	10.00	Static	No	No
		9/30/98	0.00	Static	No	Yes
		9/30/98	15.00	Static	No	No
		10/1/98	300.00	Static	Yes	No
		10/1/98	0.00	Static	No	No
		10/1/98	0.00	Static	No	No
		10/2/98	0.00	Static	No	No
		10/2/98	16.00	Static	No	No
		10/2/98	0.00	Static	No	No
		10/5/98	3.00	Static	No	No

CSSC Pharmaceuticals

Environmental Monitoring Syst m

Report Date: October 21, 1999

Facility **EMS Test Facility**
Room   **Micro Sterility Suite**

Test ID User Ref	Test Description	Test Date	Reading	Activity	TNTC	No Test
		10/5/98	8.00	Normal	No	No
		10/5/98	2.00	Static	No	No
		10/6/98	5.00	Static	No	No
		10/6/98	13.00	Static	No	No
		10/6/98	12.00	Static	No	No
		10/7/98	9.00	Static	No	No
		10/7/98	10.00	Static	No	No
		10/7/98	16.00	Static	No	No
		10/8/98	18.00	Static	No	No
		10/8/98	12.00	Static	No	No
		10/8/98	300.00	Static	Yes	No
		10/9/98	18.00	Static	No	No
		10/9/98	6.00	Normal	No	No
		10/9/98	3.00	Static	No	No
		10/12/98	3.00	Static	No	No
		10/12/98	13.00	Static	No	No
		10/12/98	8.00	Static	No	No
		10/13/98	9.00	Static	No	No
		10/13/98	9.00	Static	No	No
		10/13/98	0.00	Static	No	No
		10/14/98	8.00	Static	No	No
		10/14/98	7.00	Static	No	No
		10/14/98	0.00	Static	No	No
		10/15/98	1.00	Static	No	No
		10/15/98	2.00	Static	No	No
		10/15/98	10.00	Static	No	No
		10/16/98	1.00	Static	No	No
		10/16/98	5.00	Static	No	No
		10/16/98	1.00	Static	No	No
		10/19/98	4.00	Static	No	No
		10/19/98	13.00	Static	No	No
		10/19/98	3.00	Static	No	No
		10/20/98	17.00	Static	No	No
		10/20/98	4.00	Static	No	No
		10/20/98	1.00	Static	No	No
		10/21/98	300.00	Static	Yes	No
		10/21/98	5.00	Static	No	No
		10/21/98	5.00	Static	No	No
		10/22/98	12.00	Static	No	No
		10/22/98	7.00	Static	No	No
		10/22/98	8.00	Static	No	No

CSSC Pharmaceuticals

Micro Sterility Suite
Touch Plate

Legend:
- JSmith
- RWatson
- SBellman
- TNucci

Y-axis: 0, 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36

X-axis: 09/23/98, 09/24/98, 09/28/98, 09/30/98, 10/02/98, 10/06/98, 10/07/98, 10/09/98, 10/13/98, 10/15/98, 10/16/98
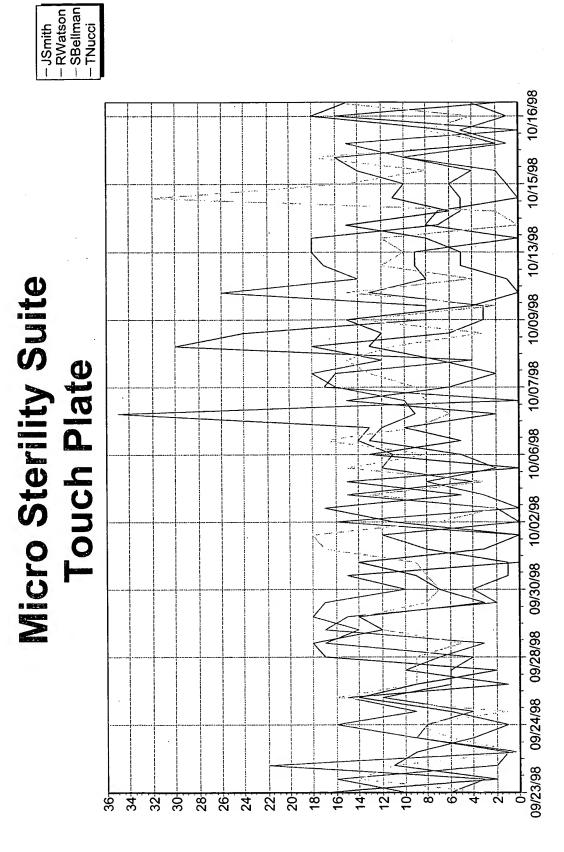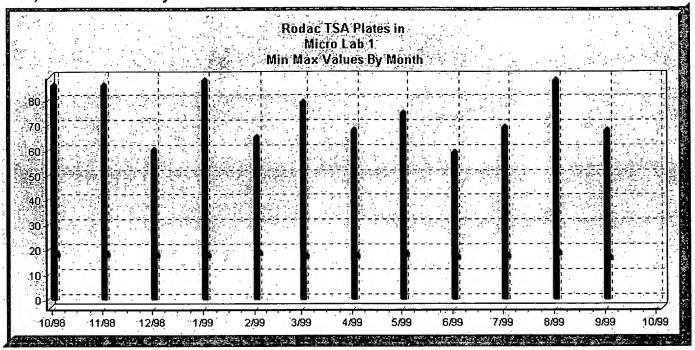
12 Month Summary for Rodac TSA Plates in Micro Lab 1

Facility:**EMS Test Facility**

Rodac TSA Plates in
Micro Lab 1
Min Max Values By Month

Min, Max, Average and number of Surveys (excludes No Test and TNTC or Non Quantifyable readings)
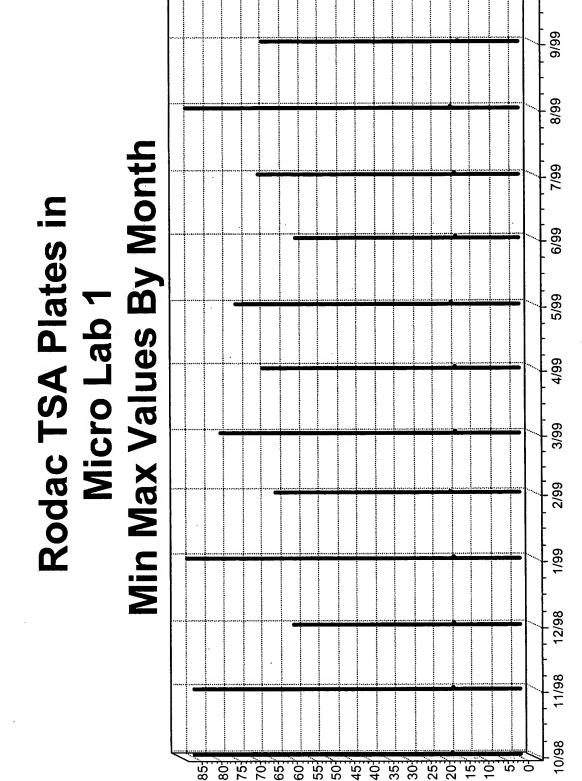
	Oct,98	Nov,98	Dec,98	Jan,99	Feb,99	Mar,99	Apr,99	May,99	Jun,99	Jul,99	Aug,99	Sep,99	Oct,99
Min	0	0	0	0	0	0	0	0	0	0	0	0	
Max	85	85	59	87	64	78	67	74	58	68	87	67	
Avg	17.42	17.27	16.82	16.96	17.87	16.51	16.51	17.44	16.23	16.57	17.65	15.58	
Count	379	354	400	359	346	388	382	362	379	380	377	276	

N Test Summary

	Oct,98	Nov,98	Dec,98	Jan,99	Feb,99	Mar,99	Apr,99	May,99	Jun,99	Jul,99	Aug,99	Sep,99	Oct,99
Count	7	10	1	6	5	7	7	6	2	7	6	8	

Alert and Action Limit Excursions
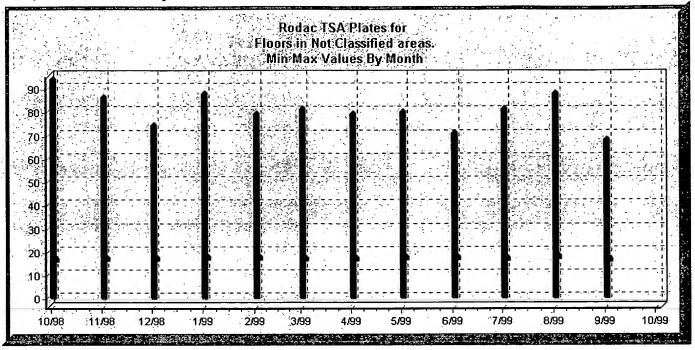
	Oct,98	Nov,98	Dec,98	Jan,99	Feb,99	Mar,99	Apr,99	May,99	Jun,99	Jul,99	Aug,99	Sep,99	Oct,99
>Alert	66	57	67	52	75	67	70	68	64	62	67	43	
>Action	31	30	38	32	30	34	26	30	30	26	35	18	
OK	292	281	308	288	250	306	293	274	300	301	288	219	

Rodac TSA Plates in
Micro Lab 1
Min Max Values By Month

12 Month Summary for Rodac TSA Plat s for Floors in Not Classifi d areas.

Facility:**EMS Test Facility**

Rodac TSA Plates for
Floors in Not Classified areas.
Min Max Values By Month

Min, Max, Average and number of Surveys (excludes No Test and TNTC or Non Quantifyable readings)

	Oct,98	Nov,98	Dec,98	Jan,99	Feb,99	Mar,99	Apr,99	May,99	Jun,99	Jul,99	Aug,99	Sep,99	Oct,99
Min	0	0	0	0	0	0	0	0	0	0	0	0	
Max	93	85	73	87	78	80	78	79	70	80	87	67	
Avg	15.78	16.2	16.14	16.45	16.8	16.16	16.28	16.53	16.59	16.3	16.87	15.97	
Count	1349	1278	1424	1289	1227	1434	1350	1283	1373	1341	1353	1007	
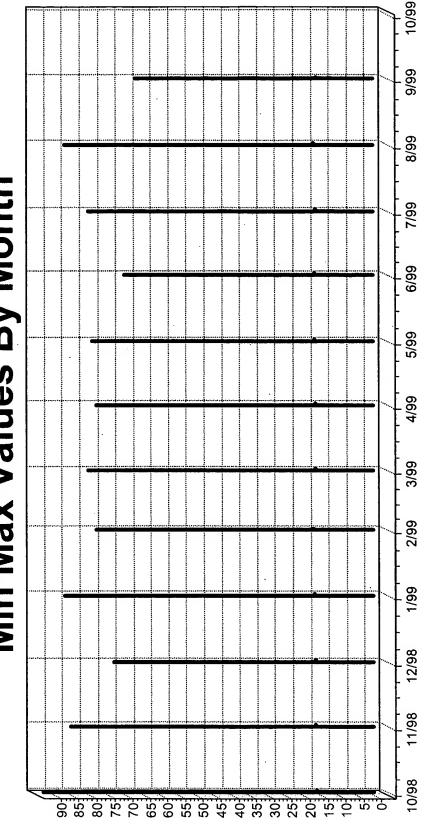
N T st Summary

	Oct,98	Nov,98	Dec,98	Jan,99	Feb,99	Mar,99	Apr,99	May,99	Jun,99	Jul,99	Aug,99	Sep,99	Oct,99
Count	25	32	29	29	30	26	30	27	25	23	18	21	

Alert and Action Limit Excursions

	Oct,98	Nov,98	Dec,98	Jan,99	Feb,99	Mar,99	Apr,99	May,99	Jun,99	Jul,99	Aug,99	Sep,99	Oct,99
>Alert	292	292	339	322	321	347	341	302	336	314	333	232	
>Action	95	110	115	93	96	108	87	109	122	114	104	78	
OK	994	915	1018	905	845	1020	948	911	961	955	951	733	

Rodac TSA Plates for
Floors in Not Classified areas.
Min Max Values By Month

Environmental Monitoring System

Report Date: 10/20/1999

Facility: **EMS Test Facility**

Product: **1234**
Lot #: **5678**

Survey Contol No. **1501** Survey Date: 7/13/99 Survey Shift: 1

Room ID: 30 RefNo Water 1 Room Description **Water Room # 1**

Water TOC

TestID/Ref	TestID	TestSite Description	TestDate TestBy	ReadDate ReadBy	SampleID Room/Activity	NoTest TNTC
POT-SPV-00 1	478	Water TOC sample taken at city line	7/13/99 12:00:00AM TestQATech	7/18/99 8:34:00AM TJoyce	+S03505A **27**	N N
ROL-SPV-00 1	262	Water TOC sample taken after RO tank (first RO loop system port)	7/13/99 12:00:00AM TestQATech	7/18/99 8:34:00AM TJoyce	+S03509A **18**	N N
ROL-SPV-00 5	267	Water TOC sample taken at 0.2 micrometer absolute filter inlet	7/13/99 12:00:00AM TestQATech	7/18/99 8:34:00AM TJoyce	+S03513A **18**	N N
ROL-SPV-00 6	268	Water TOC sample taken at 0.2 micrometer absolute filter outlet	7/13/99 12:00:00AM TestQATech	7/18/99 8:34:00AM TJoyce	+S03510A **98**	N N
ROU-SPV-00 3	259	Water TOC sample taken at RO membrane 3	7/13/99 12:00:00AM TestQATech	7/18/99 8:34:00AM TJoyce	+S03512A **22**	N N
WPL-SPV-00 5	253	Water TOC sample taken after UV unit 1	7/13/99 12:00:00AM TestQATech	7/18/99 8:34:00AM TJoyce	+S03511A **45**	N N
WPL-SPV-00 8	255	Water TOC sample taken after RO pre-filter/before overflow line	7/13/99 12:00:00AM TestQATech	7/18/99 8:34:00AM TJoyce	+S03507A **35**	N N
WPL-SPV-00 9	256	Water TOC sample taken after RO pre-filter/after overflow line (TS)	7/13/99 12:00:00AM TestQATech	7/18/99 8:34:00AM TJoyce	+S03508A **47**	N N
WPL-SPV-01 1	479	Water TOC sample taken after carbon tank	7/13/99 12:00:00AM TestQATech	7/18/99 8:34:00AM TJoyce	+S03506A **22**	N N

Reviewed By: _____ Date: _____

CSSC Pharmaceuticals

Page: 1 of 1

Environmental Monitoring System

Report Date: 10/20/99
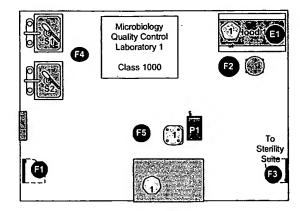
Room ID 4 Room Ref I **MicroLab1**

Room Description

Micro Lab 1

Test ID	Test UserRef	Test Description	Alert Limit	Action Limit	Test Date	Shift	Reading	Condition
15	F3	Floor site in doorway - to sterility suite.	25	30	09-01-1999	1	100	> Action
19	S1	Swab sample within sink 1.	40	50	09-01-1999	1	93	> Action
19	S1	Swab sample within sink 1.	40	50	09-03-1999	1	89	> Action
13	F1	Floor site in doorway - room entrance.	25	30	09-06-1999	3	39	> Action
20	S2	Swab sample within sink 2.	40	50	09-06-1999	2	54	> Action
21	1	Fallout plate within laminar flow hood.	2	3	09-06-1999	3	5	> Action
14	F2	Floor site in front of laminar flow hood.	25	30	09-07-1999	2	100	> Action
16	F4	Floor site in front of sinks.	35	45	09-07-1999	3	100	> Action
19	S1	Swab sample within sink 1.	40	50	09-07-1999	2	300	> Action
23	1	Airborne contamination count taken in center of room.	30	40	09-07-1999	2	300	> Action
23	1	Airborne contamination count taken in center of room.	30	40	09-07-1999	3	61	> Action
17	F5	Floor site in center of room.	25	30	09-08-1999	1	58	> Acti n
18	E1	Site on work surface of laminar flow hood.	15	20	09-08-1999	3	33	> Action
23	1	Airborne contamination count taken in center of room.	30	40	09-09-1999	3	300	> Acti n
16	F4	Floor site in front of sinks.	35	45	09-10-1999	3	67	> Acti n
21	1	Fallout plate within laminar flow hood.	2	3	09-10-1999	1	300	> Action
18	E1	Site on work surface of laminar flow hood.	15	20	09-13-1999	2	34	> Acti n
19	S1	Swab sample within sink 1.	40	50	09-13-1999	2	300	> Action
16	F4	Floor site in front of sinks.	35	45	09-14-1999	2	59	> Action
23	1	Airborne contamination count taken in center of room.	30	40	09-14-1999	1	300	> Action
13	F1	Floor site in doorway - room entrance.	25	30	09-15-1999	1	53	> Action
13	F1	Floor site in doorway - room entrance.	25	30	09-15-1999	3	56	> Action
15	F3	Floor site in doorway - to sterility suite.	25	30	09-15-1999	3	56	> Action
18	E1	Site on work surface of laminar flow hood.	15	20	09-15-1999	3	26	> Action
21	1	Fallout plate within laminar flow hood.	2	3	09-15-1999	2	5	> Action
23	1	Airborne contamination count taken in center of room.	30	40	09-15-1999	1	50	> Action
13	F1	Floor site in doorway - room entrance.	25	30	09-16-1999	1	46	> Action
13	F1	Floor site in doorway - room entrance.	25	30	09-16-1999	3	31	> Action
17	F5	Floor site in center of room.	25	30	09-16-1999	1	58	> Action

Environmental Monitoring System

Report Date: 10/20/99

23	1	Airborne contamination count taken in center of room.	30	40	09-16-1999	3	300	> Action
13	F1	Floor site in doorway - room entrance.	25	30	09-17-1999	2	51	> Action
21	1	Fallout plate within laminar flow hood.	2	3	09-17-1999	1	4	> Action
23	1	Airborne contamination count taken in center of room.	30	40	09-17-1999	1	44	> Action
23	1	Airborne contamination count taken in center of room.	30	40	09-17-1999	3	78	> Action
18	E1	Site on work surface of laminar flow hood.	15	20	09-20-1999	1	100	> Action
19	S1	Swab sample within sink 1.	40	50	09-20-1999	2	300	> Action
20	S2	Swab sample within sink 2.	40	50	09-20-1999	1	300	> Action
21	1	Fallout plate within laminar flow hood.	2	3	09-21-1999	1	5	> Action
20	S2	Swab sample within sink 2.	40	50	09-22-1999	2	71	> Action

Environmental Monitoring System

Report Date: 10/20/99
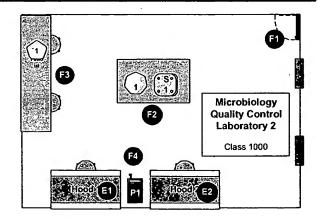
Room ID 5 Room Ref I **MicroLab2**

Room Description
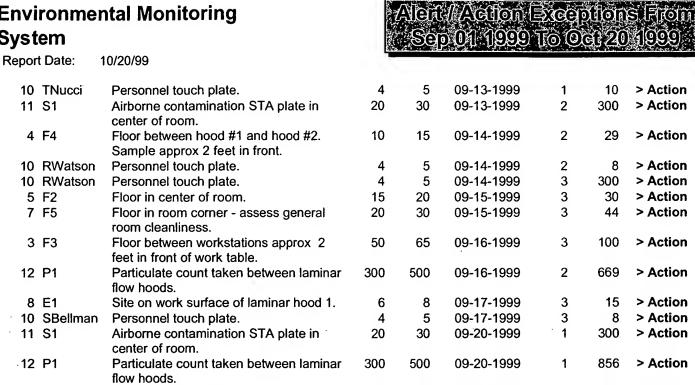
Micro Lab2

Microbiology
Quality Control
Laboratory 2

Class 1000

Test ID	Test UserRef	Test Description	Alert Limit	Action Limit	Test Date	Shift	Reading	Condition
8	E1	Site on work surface of laminar hood 1.	6	8	09-01-1999	2	100	> Action
8	E1	Site on work surface of laminar hood 1.	6	8	09-01-1999	3	15	> Action
10	RWatson	Personnel touch plate.	4	5	09-01-1999	1	300	> Action
10	TNucci	Personnel touch plate.	4	5	09-01-1999	1	8	> Action
11	S1	Airborne contamination STA plate in center of room.	20	30	09-01-1999	1	60	> Action
11	S1	Airborne contamination STA plate in center of room.	20	30	09-01-1999	3	300	> Action
5	F2	Floor in center of room.	15	20	09-02-1999	1	100	> Action
9	E2	Site on work surface of laminar hood 2.	6	8	09-02-1999	3	12	> Action
10	SBellman	Personnel touch plate.	4	5	09-02-1999	1	6	> Action
11	S1	Airborne contamination STA plate in center of room.	20	30	09-02-1999	1	300	> Action
3	F3	Floor between workstations approx 2 feet in front of work table.	50	65	09-03-1999	1	100	> Action
4	F4	Floor between hood #1 and hood #2. Sample approx 2 feet in front.	10	15	09-03-1999	1	100	> Action
5	F2	Floor in center of room.	15	20	09-03-1999	1	27	> Action
8	E1	Site on work surface of laminar hood 1.	6	8	09-03-1999	2	100	> Action
10	TNucci	Personnel touch plate.	4	5	09-03-1999	1	300	> Action
4	F4	Floor between hood #1 and hood #2. Sample approx 2 feet in front.	10	15	09-06-1999	2	100	> Action
6	F1	Floor in doorway / room entrance	15	20	09-06-1999	3	25	> Action
6	F1	Floor in doorway / room entrance	15	20	09-07-1999	2	24	> Action
7	F5	Floor in room corner - assess general room cleanliness.	20	30	09-07-1999	2	52	> Action
10	SBellman	Personnel touch plate.	4	5	09-07-1999	2	300	> Action
3	F3	Floor between workstations approx 2 feet in front of work table.	50	65	09-09-1999	2	85	> Action
10	RWatson	Personnel touch plate.	4	5	09-09-1999	1	6	> Action
10	TNucci	Personnel touch plate.	4	5	09-09-1999	2	300	> Action
3	F3	Floor between workstations approx 2 feet in front of work table.	50	65	09-10-1999	1	100	> Action
10	JSmith	Personnel touch plate.	4	5	09-10-1999	3	7	> Action
5	F2	Floor in center of room.	15	20	09-13-1999	2	100	> Action
9	E2	Site on work surface of laminar hood 2.	6	8	09-13-1999	2	16	> Action
9	E2	Site on work surface of laminar hood 2.	6	8	09-13-1999	3	100	> Action

Environmental Monitoring System

Report Date: 10/20/99

10	TNucci	Personnel touch plate.	4	5	09-13-1999	1	10	> Action
11	S1	Airborne contamination STA plate in center of room.	20	30	09-13-1999	2	300	> Action
4	F4	Floor between hood #1 and hood #2. Sample approx 2 feet in front.	10	15	09-14-1999	2	29	> Action
10	RWatson	Personnel touch plate.	4	5	09-14-1999	2	8	> Action
10	RWatson	Personnel touch plate.	4	5	09-14-1999	3	300	> Action
5	F2	Floor in center of room.	15	20	09-15-1999	3	30	> Action
7	F5	Floor in room corner - assess general room cleanliness.	20	30	09-15-1999	3	44	> Action
3	F3	Floor between workstations approx 2 feet in front of work table.	50	65	09-16-1999	3	100	> Action
12	P1	Particulate count taken between laminar flow hoods.	300	500	09-16-1999	2	669	> Action
8	E1	Site on work surface of laminar hood 1.	6	8	09-17-1999	3	15	> Action
10	SBellman	Personnel touch plate.	4	5	09-17-1999	3	8	> Action
11	S1	Airborne contamination STA plate in center of room.	20	30	09-20-1999	1	300	> Action
12	P1	Particulate count taken between laminar flow hoods.	300	500	09-20-1999	1	856	> Action
3	F3	Floor between workstations approx 2 feet in front of work table.	50	65	09-22-1999	1	100	> Action
7	F5	Floor in room corner - assess general room cleanliness.	20	30	09-22-1999	2	55	> Action
10	SBellman	Personnel touch plate.	4	5	09-22-1999	2	9	> Action

Environmental Monitoring System

Report Date: 10/21/99

Room/Area: **Micro Gowning Area**

Legend (per cell, top to bottom): Min / Max / Count / Average

Site	Stat	1998 9	1998 10	1998 11	1998 12	1998 Total	1999 1	1999 2	1999 3	1999 4	1999 5	1999 6	1999 7	1999 8	1999 9	1999 Total	Total
Floor site in doorway - room entrance.	Min	0	0	0	2	0	0	1	0	0	0	1	0	0	0	0	0
	Max	100	100	100	100	100	100	75	100	41	100	100	100	100	100	100	100
	Count	20	68	64	73	225	66	62	71	66	62	69	69	68	51	584	809
	Average	23	25	29	26		21	21	22	20	27	25	24	26	26		
Floor site in doorway leading to controlled area.	Min	1	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
	Max	38	100	100	34	100	100	100	100	38	100	100	100	100	100	100	100
	Count	20	69	65	72	226	66	62	74	68	66	70	70	67	52	595	821
	Average	13	13	13	10		14	15	12	11	14	17	16	14	18		
Floor site on clean site of bench designating class transition area.	Min	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Max	50	100	100	100	100	100	46	38	35	100	100	100	100	100	100	100
	Count	20	70	67	73	230	65	62	74	67	65	67	70	70	52	592	822
	Average	17	14	18	17		15	15	14	14	20	17	16	17	15		
Floor site on wash side of bench designating class transition area.	Min	1	0	0	0	0	1	0	1	0	0	0	0	0	1	0	0
	Max	61	100	100	100	100	100	44	80	100	100	100	100	100	100	100	100
	Count	18	70	66	73	227	66	63	71	68	66	70	67	70	49	590	817
	Average	22	22	25	20		20	19	24	24	30	23	25	23	29		
Particulate count taken in center of clean area.	Min	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Max	10	9	10	10	10	9	10	9	10	8	10	8	6	7	10	10
	Count	19	70	65	72	226	66	64	72	70	66	69	69	70	50	596	822
	Average	3	3	3	3		3	2	3	3	3	3	3	2	2		
Particulate count taken in center of wash area.	Min	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Max	11	10	8	13	13	11	12	10	11	9	11	13	13	12	13	13
	Count	20	70	65	73	228	65	62	72	70	67	69	69	68	52	594	822
	Average	4	3	4	3		4	4	3	4	4	3	4	3	4		
RCS airborne contamination sample taken in center of clean area.	Min	0	0	0	0	0	0	0	0	1	0	0	0	0	1	0	0
	Max	76	300	300	300	300	300	300	300	300	300	77	300	300	300	300	300
	Count	19	69	64	74	226	66	61	72	70	64	71	69	70	51	594	820
	Average	22	24	26	38		46	26	25	27	37	21	38	28	37		
RCS airborne contamination sample taken in center of wash area.	Min	2	0	0	2	0	0	1	1	0	0	0	0	0	2	0	0
	Max	300	96	300	93	300	300	300	300	300	93	300	300	300	300	300	300
	Count	20	69	67	73	229	67	62	73	68	66	71	69	69	50	595	824
	Average	75	30	31	29		37	43	31	35	25	36	39	38	40		
Swab sample within sink 1.	Min	0	0	2	0	0	0	0	0	0	1	4	0	1	2	0	0
	Max	300	300	300	300	300	300	300	300	300	300	300	300	300	142	300	300
	Count	20	69	66	73	228	65	61	74	69	66	71	67	68	51	592	820
	Average	67	56	41	47		59	52	49	40	63	49	44	46	43		
Swab sample within sink 2.	Min	0	0	1	0	0	0	2	1	0	0	0	0	2	1	0	0
	Max	93	122	300	300	300	300	119	300	300	300	300	300	300	300	300	300
	Count	20	69	66	71	226	65	64	73	68	67	69	69	68	52	595	821
	Average	41	41	47	48		66	41	53	47	57	49	52	51	39		

Min / Max / Count / Average

Environmental Monitoring System

Report Date: 10/21/99

12 Month Historical Data By Room or Area

Legend: Min / Max / Count / Average

	1998 9	10	11	12	1998 Total	1999 1	2	3	4	5	6	7	8	9	1999 Total	Total
Wall site near door leading to controlled area.																
Min	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Max	43	100	100	100	100	100	100	100	100	100	100	100	100	54	100	100
Count	19	67	64	73	223	66	62	73	68	66	69	67	69	51	591	814
Average	14	21	22	27		22	21	25	22	19	22	20	22	19		
Wall site near doorway - room entrance.																
Min	1	1	0	1	0	0	1	2	0	0	0	0	0	1	0	0
Max	100	100	100	100	100	83	100	100	100	100	100	100	100	100	100	100
Count	19	67	66	74	226	66	63	74	69	66	69	69	67	49	592	818
Average	30	28	29	28		23	25	34	32	25	24	25	27	28		
Wall site on near wall - general cleanliness assessment.																
Min	0	1	0	0	0	2	1	1	1	3	0	0	0	2	0	0
Max	51	126	124	124	126	100	114	127	123	108	118	126	121	87	127	127
Count	20	70	65	72	227	65	63	74	68	66	69	69	67	49	590	817
Average	26	44	40	37		35	36	39	37	38	34	35	41	37		
Total																
Min	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Max	300	300	300	300	300	300	300	300	300	300	300	300	300	300	300	300
Count	254	897	850	946	2,947	854	811	947	889	853	903	893	891	659	7,700	10,647

Min
Max
Count
Average

Environmental Monitoring System

Report Date: 10/21/99

Room/Area: **Micro Lab 1**

Measurement	Stat	1998 9	1998 10	1998 11	1998 12	1998 Total	1999 1	1999 2	1999 3	1999 4	1999 5	1999 6	1999 7	1999 8	1999 9	1999 Total	Total
Airborne contamination count taken in center of room.	Min	6	0	0	1	0	1	0	0	0	0	1	0	0	0	0	0
	Max	300	300	300	300	300	300	300	300	300	300	300	300	300	300	300	300
	Count	18	66	62	68		63	59	67	66	62	65	65	64	46		
	Average	40	23	39	32	214	32	23	26	27	35	31	34	45	48	557	771
Fallout plate within laminar flow hood.	Min	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Max	5	300	6	300	300	300	300	300	300	300	300	5	300	300	300	300
	Count	18	65	63	69		62	59	68	65	62	65	65	64	48		
	Average	2	15	2	6	215	11	7	10	11	6	6	2	7	8	558	773
Floor site in center of room.	Min	0	0	0	0	0	0	0	1	0	1	0	1	1	1	0	0
	Max	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
	Count	18	64	61	69		60	60	67	64	61	65	64	63	47		
	Average	18	17	19	18	212	20	20	22	15	20	21	23	18	16	551	763
Floor site in doorway - room entrance.	Min	2	0	0	1	0	0	0	0	0	0	0	1	0	0	0	0
	Max	55	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
	Count	18	65	63	69		63	59	68	64	62	66	62	65	45		
	Average	17	23	25	20	215	23	21	22	21	19	17	18	23	20	554	769
Floor site in doorway - to sterility suite.	Min	0	0	0	0	0	0	0	0	1	0	0	0	0	1	0	0
	Max	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
	Count	17	65	61	69		62	59	69	66	63	66	66	66	46		
	Average	22	19	21	21	212	17	19	19	18	18	19	17	17	16	563	775
Floor site in front of laminar flow hood.	Min	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
	Max	58	100	100	100	100	41	100	100	100	100	100	100	100	100	100	100
	Count	18	63	61	69		63	59	67	65	62	66	66	65	47		
	Average	23	19	22	21	211	16	20	19	15	24	17	18	21	14	560	771
Floor site in front of sinks.	Min	1	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0
	Max	88	85	85	100	100	100	100	100	100	74	100	100	100	100	100	100
	Count	18	66	60	68		62	58	68	65	62	66	65	66	47		
	Average	28	26	24	23	212	32	26	25	25	26	29	25	28	22	559	771
Particulate count taken in room center.	Min	46	0	0	0	0	0	0	0	29	0	0	0	0	12	0	0
	Max	3,423	2,318	3,542	3,617	3,617	3,472	1,889	3,509	2,700	1,886	3,689	3,591	3,687	1,763	3,689	3,689
	Count	18	64	63	65		61	59	67	64	62	65	65	65	48		
	Average	1,279	864	1,109	1,081	210	1,077	918	992	1,090	804	990	906	1,163	925	556	766
Settling plate taken on work surface.	Min	3	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
	Max	48	300	300	300	300	300	300	300	300	300	300	300	300	30	300	300
	Count	17	65	63	67		53	58	53	66	63	63	65	66	47		
	Average	17	23	27	25	212	17	27	17	20	29	26	21	33	14	557	769
Site on work surface of laminar flow hood.	Min	2	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0
	Max	100	100	100	100	100	100	100	100	100	37	100	100	100	100	100	100
	Count	18	66	62	69		62	60	68	65	62	65	66	65	48		
	Average	18	13	12	13	215	12	14	16	14	9	13	10	15	13	561	776

Legend: Min / Max / Count / Average

Environmental Monitoring System

Report Date: 10/21/99

12 Month Historical Data By Room or Area

Location	Metric	1998 9	10	11	12	Total	1999 1	2	3	4	5	6	7	8	9	Total	Total
Swab sample within sink 1.	Min	0	0	1	1	0	1	0	1	0	0	0	0	0	0	0	0
	Max	86	300	300	300	300	300	300	300	300	300	300	300	300	300	300	300
	Count	18	64	62	65	209	63	58	68	65	62	64	64	66	46	556	765
	Average	30	33	33	32		41	40	28	32	40	38	47	26	46		
Swab sample within sink 2.	Min	2	0	0	0	0	2	0	1	0	2	0	0	3	1	0	0
	Max	300	300	300	300	300	300	300	300	300	300	300	300	300	300	300	300
	Count	18	66	62	66	212	60	60	69	66	60	63	65	66	47	556	768
	Average	56	93	59	87		43	44	43	26	47	29	33	38	34		
Total	Min	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Max	3,423	2,318	3,542	3,617	3,617	3,472	1,889	3,509	2,700	1,886	3,689	3,591	3,687	1,763	3,689	3,689
	Count	214	779	743	813	2,549	743	708	813	781	743	779	778	781	562	6,688	9,237

Legend:
Min
Max
Count
Average

Environmental Monitoring System

Report Date: 10/21/99

Room/Area: **Micro Lab2**

Description	Metric	1998 9	10	11	12	Total	1999 1	2	3	4	5	6	7	8	9	Total	Total
Airborne contamination STA plate in center of room.	Min	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Max	49	300	52	300	300	300	41	300	300	58	300	300	300	300	300	300
	Count	18	65	63	69		60	58	68	65	63	65	65	66	48		
	Average	15	30	18	23	215	35	17	29	39	17	27	24	25	39	558	773
Floor between hood #1 and hood #2. Sample approx 2 feet in front.	Min	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Max	15	100	100	100	100	100	100	24	100	100	100	100	25	100	100	100
	Count	17	65	61	69		61	59	67	66	60	64	65	66	48		
	Average	7	10	11	13	212	14	10	8	10	9	13	14	8	12	556	768
Floor between workstations approx 2 feet in front of work table.	Min	1	1	1	0	0	0	0	0	0	3	0	1	0	6	0	0
	Max	108	100	114	123	123	111	100	101	122	130	127	122	114	100	130	130
	Count	18	64	62	69		62	59	69	66	63	64	64	66	47		
	Average	36	36	40	41	213	40	34	43	36	35	42	33	36	44	560	773
Floor in center of room.	Min	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
	Max	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
	Count	18	65	63	68		62	60	66	65	63	64	66	64	48		
	Average	30	12	18	14	214	13	17	19	14	14	13	14	12	14	558	772
Floor in doorway / room entrance	Min	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Max	38	100	100	100	100	100	100	100	100	100	40	100	100	25	100	100
	Count	17	66	62	68		62	57	68	64	63	64	66	66	46		
	Average	13	15	13	13	213	15	12	13	15	15	11	13	15	9	556	769
Floor in room corner - assess general room cleanliness.	Min	1	0	0	0	0	0	1	0	0	0	0	0	1	1	0	0
	Max	40	100	60	100	100	100	100	100	100	100	52	48	55	55	100	100
	Count	18	66	62	67		63	58	68	65	63	66	63	65	48		
	Average	13	20	15	19	213	21	20	16	18	19	17	16	19	17	559	772
Particulate count taken between laminar flow hoods.	Min	0	0	5	0	0	0	0	0	0	0	0	16	0	0	0	0
	Max	487	945	683	733	945	743	950	873	720	986	842	950	930	856	986	986
	Count	17	65	62	68		62	60	67	64	63	65	63	65	47		
	Average	257	267	288	279	212	247	271	272	223	290	232	330	282	225	556	768
Personnel touch plate.	Min	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Max	300	300	300	300	300	300	300	300	300	300	300	300	300	300	300	300
	Count	72	256	248	270		250	234	273	259	244	260	257	260	185		
	Average	11	13	12	11	846	12	8	9	14	16	13	16	11	11	2,222	3,068
Site on work surface of laminar hood 1.	Min	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Max	16	100	15	100	100	100	11	100	16	100	100	100	100	100	100	100
	Count	18	66	60	68		60	59	68	64	62	64	66	65	48		
	Average	6	8	4	6	212	9	5	6	4	9	9	7	7	9	556	768
Site on work surface of laminar hood 2.	Min	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Max	13	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
	Count	16	65	61	68		63	58	66	65	61	66	65	65	47		
	Average	4	9	6	12	210	13	6	8	6	6	8	9	8	6	556	766

Legend:
Min
Max
Count
Average

Environmental Monitoring System

Report Date: 10/21/99

| | | 1998 | | | | 1999 | | | | | | | | | | | Total | |
	9	10	11	12	Total	1	2	3	4	5	6	7	8	9	Total	
Total	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	487	945	683	733	945	743	950	873	720	986	842	950	930	856	986	986
	229	843	804	884	2,760	805	762	880	843	805	842	840	848	612	7,237	9,997

| Min |
| Max |
| Count |
| Average |

CSSC Pharmaceuticals

Environmental Monitoring System

Facility: EMS T st Facility

Report Date: 10/21/99

Rodac TSA Plate

Micro Gowning Area		1998 10	1998 11	1998 12	1998 Total	1999 1	1999 2	1999 3	1999 4	1999 5	1999 6	1999 7	1999 8	1999 9	1999 Total	Total
	Floor site in doorway - room entrance.	0 / 100 / 25.00 / 68	0 / 100 / 29.00 / 64	2 / 100 / 26.00 / 73	0 / 100 / 205	0 / 100 / 21.00 / 66	1 / 75 / 21.00 / 62	0 / 100 / 22.00 / 71	0 / 41 / 20.00 / 66	0 / 100 / 27.00 / 62	1 / 100 / 25.00 / 69	0 / 100 / 24.00 / 69	0 / 100 / 26.00 / 68	0 / 100 / 26.00 / 51	0 / 100 / 584	0 / 100 / 789
	Floor site in doorway leading to controlled area.	0 / 100 / 13.00 / 69	0 / 100 / 13.00 / 65	0 / 34 / 10.00 / 72	0 / 100 / 206	0 / 100 / 14.00 / 66	0 / 100 / 15.00 / 62	0 / 100 / 12.00 / 74	0 / 38 / 11.00 / 68	0 / 100 / 14.00 / 66	0 / 100 / 17.00 / 70	0 / 100 / 16.00 / 70	1 / 100 / 14.00 / 67	0 / 100 / 18.00 / 52	0 / 100 / 595	0 / 100 / 801
	Floor site on clean site of bench designating clas	0 / 100 / 14.00 / 70	0 / 100 / 18.00 / 67	0 / 100 / 17.00 / 73	0 / 100 / 210	0 / 100 / 15.00 / 65	0 / 46 / 15.00 / 62	0 / 38 / 14.00 / 74	0 / 35 / 14.00 / 67	0 / 100 / 20.00 / 65	0 / 100 / 17.00 / 67	0 / 100 / 16.00 / 70	0 / 100 / 17.00 / 70	0 / 100 / 15.00 / 52	0 / 100 / 592	0 / 100 / 802
	Floor site on wash side of bench designating clas	1 / 100 / 22.00 / 67	0 / 100 / 25.00 / 66	0 / 100 / 20.00 / 73	0 / 100 / 209	1 / 100 / 20.00 / 66	0 / 44 / 19.00 / 63	1 / 80 / 24.00 / 71	0 / 100 / 24.00 / 68	0 / 100 / 30.00 / 66	0 / 100 / 23.00 / 70	0 / 100 / 25.00 / 67	0 / 100 / 23.00 / 70	1 / 100 / 29.00 / 49	0 / 100 / 590	0 / 100 / 799
	Wall site near door leading to controlled area.	1 / 100 / 21.00 / 67	0 / 100 / 22.00 / 64	0 / 100 / 27.00 / 73	0 / 100 / 204	0 / 100 / 22.00 / 66	0 / 100 / 21.00 / 62	0 / 100 / 25.00 / 73	0 / 100 / 22.00 / 68	0 / 100 / 19.00 / 66	0 / 100 / 22.00 / 69	0 / 100 / 20.00 / 67	0 / 100 / 22.00 / 69	0 / 54 / 19.00 / 51	0 / 100 / 591	0 / 100 / 795
	Wall site near doorway - room entrance.	1 / 100 / 28.00 / 67	0 / 100 / 29.00 / 66	1 / 100 / 28.00 / 74	0 / 100 / 207	0 / 83 / 23.00 / 66	1 / 100 / 25.00 / 63	2 / 100 / 34.00 / 74	0 / 100 / 32.00 / 69	0 / 100 / 25.00 / 66	0 / 100 / 24.00 / 69	0 / 100 / 25.00 / 69	0 / 100 / 27.00 / 67	1 / 100 / 28.00 / 49	0 / 100 / 592	0 / 100 / 799
	Wall site on near wall - general cleanliness ass	1 / 126 / 44.00 / 70	0 / 124 / 40.00 / 65	0 / 124 / 37.00 / 72	0 / 126 / 207	2 / 100 / 35.00 / 65	1 / 114 / 36.00 / 63	1 / 127 / 39.00 / 74	1 / 123 / 37.00 / 68	3 / 108 / 38.00 / 66	0 / 118 / 34.00 / 69	0 / 126 / 35.00 / 69	0 / 121 / 41.00 / 67	2 / 87 / 37.00 / 49	0 / 127 / 590	0 / 127 / 797
	Total	0 / 126 / 481	0 / 124 / 457	0 / 124 / 510	0 / 126 / 508 / 1,448	0 / 100 / 460	0 / 114 / 437	0 / 127 / 511	0 / 123 / 474	0 / 108 / 457	0 / 118 / 483	0 / 126 / 481	0 / 121 / 478	0 / 100 / 353	0 / 127 / 1,472 / 4,134	0 / 127 / 5,582

CSSC Pharmaceuticals

Environmental Monitoring System

Facility: **EMS T st Facility**

Report Date: 10/21/99

		1998 10	11	12	Total	1999 1	2	3	4	5	6	7	8	9	Total	Total
Micro Lab 1	Floor site in center of room.	0 / 100 / 17.00 / 64	0 / 100 / 19.00 / 61	0 / 100 / 18.00 / 69	0 / 100 / 194	0 / 100 / 20.00 / 60	0 / 100 / 20.00 / 60	1 / 100 / 22.00 / 67	0 / 46 / 15.00 / 64	1 / 100 / 20.00 / 61	0 / 100 / 21.00 / 65	1 / 100 / 23.00 / 64	1 / 60 / 18.00 / 63	1 / 58 / 16.00 / 47	0 / 100 / 551	0 / 100 / 745
	Floor site in doorway - room entrance.	0 / 100 / 23.00 / 65	0 / 100 / 25.00 / 63	1 / 100 / 20.00 / 69	0 / 100 / 197	0 / 100 / 23.00 / 63	0 / 100 / 21.00 / 59	0 / 100 / 22.00 / 68	0 / 100 / 21.00 / 64	0 / 100 / 19.00 / 62	0 / 100 / 17.00 / 66	1 / 100 / 18.00 / 62	0 / 100 / 23.00 / 65	0 / 56 / 20.00 / 45	0 / 100 / 554	0 / 100 / 751
	Floor site in doorway - to sterility suite.	0 / 100 / 19.00 / 65	0 / 100 / 21.00 / 61	0 / 100 / 21.00 / 69	0 / 100 / 195	0 / 100 / 17.00 / 62	0 / 100 / 19.00 / 59	0 / 100 / 19.00 / 69	1 / 100 / 18.00 / 66	0 / 100 / 18.00 / 63	0 / 100 / 19.00 / 66	0 / 100 / 17.00 / 66	0 / 100 / 17.00 / 66	1 / 100 / 16.00 / 46	0 / 100 / 563	0 / 100 / 758
	Floor site in front of laminar flow hood.	1 / 100 / 19.00 / 63	1 / 100 / 22.00 / 61	0 / 100 / 21.00 / 69	0 / 100 / 193	0 / 41 / 16.00 / 63	0 / 100 / 20.00 / 59	0 / 100 / 19.00 / 67	0 / 100 / 15.00 / 65	0 / 100 / 24.00 / 62	0 / 100 / 17.00 / 66	0 / 100 / 18.00 / 66	0 / 100 / 21.00 / 65	0 / 100 / 14.00 / 47	0 / 100 / 560	0 / 100 / 753
	Floor site in front of sinks.	1 / 85 / 26.00 / 66	0 / 85 / 24.00 / 60	0 / 100 / 23.00 / 68	0 / 100 / 194	1 / 100 / 32.00 / 62	0 / 100 / 26.00 / 58	0 / 100 / 25.00 / 68	0 / 100 / 25.00 / 65	0 / 74 / 26.00 / 62	0 / 100 / 29.00 / 66	0 / 100 / 25.00 / 65	0 / 100 / 28.00 / 66	0 / 100 / 22.00 / 47	0 / 100 / 559	0 / 100 / 753
	Site on work surface of laminar flow hood.	0 / 100 / 13.00 / 66	0 / 100 / 12.00 / 62	0 / 100 / 13.00 / 69	0 / 100 / 197	0 / 100 / 12.00 / 62	1 / 100 / 14.00 / 60	0 / 100 / 16.00 / 68	0 / 100 / 14.00 / 65	0 / 37 / 9.00 / 62	0 / 100 / 13.00 / 65	0 / 100 / 10.00 / 66	0 / 100 / 15.00 / 65	0 / 100 / 13.00 / 48	0 / 100 / 561	0 / 100 / 758
	Total	0 / 100 / 389	0 / 100 / 368	0 / 100 / 413	0 / 100 / 356 / 1,170	0 / 100 / 372	0 / 100 / 355	0 / 100 / 407	0 / 100 / 389	0 / 100 / 372	0 / 100 / 394	0 / 100 / 389	0 / 100 / 390	0 / 100 / 280	0 / 100 / 1,038 / 3,348	0 / 100 / 4,518
Micro Lab2	Floor between hood #1 and hood #2. Sample approx ¿	0 / 100 / 10.00 / 65	0 / 100 / 11.00 / 61	0 / 100 / 13.00 / 69	0 / 100 / 195	0 / 100 / 14.00 / 61	0 / 100 / 10.00 / 59	0 / 24 / 8.00 / 67	0 / 100 / 10.00 / 66	0 / 100 / 9.00 / 60	0 / 100 / 13.00 / 64	0 / 100 / 14.00 / 65	0 / 25 / 8.00 / 66	0 / 100 / 12.00 / 48	0 / 100 / 556	0 / 100 / 751
	Floor between workstations approx 2 feet in front of work tab	1 / 100 / 36.00 / 64	1 / 114 / 40.00 / 62	0 / 123 / 41.00 / 69	0 / 123 / 195	0 / 111 / 40.00 / 62	0 / 100 / 34.00 / 59	0 / 101 / 43.00 / 69	0 / 122 / 36.00 / 66	3 / 130 / 35.00 / 63	0 / 127 / 42.00 / 64	1 / 122 / 33.00 / 64	0 / 114 / 36.00 / 66	6 / 100 / 44.00 / 47	0 / 130 / 560	0 / 130 / 755

Environmental Monitoring System

Facility: **EMS Test Facility**

Report Date: 10/21/99

12 Month Summary By Test Type

Each cell lists: count / percent / mean / n

		1998 10	1998 11	1998 12	1998 Total	1999 1	1999 2	1999 3	1999 4	1999 5	1999 6	1999 7	1999 8	1999 9	1999 Total	Total
Micro Lab2	Floor in center of room.	0 / 100 / 12.00 / 65	0 / 100 / 18.00 / 63	0 / 100 / 14.00 / 68	0 / 100 / 196	0 / 100 / 13.00 / 62	0 / 100 / 17.00 / 60	0 / 100 / 19.00 / 66	0 / 100 / 14.00 / 65	0 / 100 / 14.00 / 63	0 / 100 / 13.00 / 64	0 / 100 / 14.00 / 66	0 / 100 / 12.00 / 64	1 / 100 / 14.00 / 48	0 / 100 / 558	0 / 100 / 754
	Floor in doorway / room entrance	0 / 100 / 15.00 / 66	0 / 100 / 13.00 / 62	0 / 100 / 13.00 / 68	0 / 100 / 196	0 / 100 / 15.00 / 62	0 / 100 / 12.00 / 57	0 / 100 / 13.00 / 68	0 / 100 / 15.00 / 64	0 / 100 / 15.00 / 63	0 / 40 / 11.00 / 64	0 / 100 / 13.00 / 66	0 / 100 / 15.00 / 66	0 / 25 / 9.00 / 46	0 / 100 / 556	0 / 100 / 752
	Floor in room corner - assess general room cleanliness.	0 / 100 / 20.00 / 66	0 / 60 / 15.00 / 62	0 / 100 / 19.00 / 67	0 / 100 / 195	0 / 100 / 21.00 / 63	1 / 100 / 20.00 / 58	0 / 100 / 16.00 / 68	0 / 100 / 18.00 / 65	0 / 100 / 19.00 / 63	0 / 52 / 17.00 / 66	0 / 48 / 16.00 / 63	1 / 55 / 19.00 / 65	1 / 55 / 17.00 / 48	0 / 100 / 559	0 / 100 / 754
	Site on work surface of laminar hood 1.	0 / 100 / 8.00 / 66	0 / 15 / 4.00 / 60	0 / 100 / 6.00 / 68	0 / 100 / 194	0 / 100 / 9.00 / 60	0 / 11 / 5.00 / 59	0 / 100 / 6.00 / 68	0 / 16 / 4.00 / 64	0 / 100 / 9.00 / 62	0 / 100 / 9.00 / 64	0 / 100 / 7.00 / 66	0 / 100 / 7.00 / 65	0 / 100 / 9.00 / 48	0 / 100 / 556	0 / 100 / 750
	Site on work surface of laminar hood 2.	0 / 100 / 9.00 / 65	0 / 100 / 6.00 / 61	0 / 100 / 12.00 / 68	0 / 100 / 194	0 / 100 / 13.00 / 63	0 / 100 / 6.00 / 58	0 / 100 / 8.00 / 66	0 / 100 / 6.00 / 65	0 / 100 / 6.00 / 61	0 / 100 / 8.00 / 66	0 / 100 / 9.00 / 65	0 / 100 / 8.00 / 65	0 / 100 / 6.00 / 47	0 / 100 / 556	0 / 100 / 750
	Total	0 / 100 / 457	0 / 114 / 431	0 / 123 / 477	0 / 123 / 334 / 1,365	0 / 111 / 433	0 / 100 / 410	0 / 101 / 472	0 / 122 / 455	0 / 130 / 435	0 / 127 / 452	0 / 122 / 455	0 / 114 / 457	0 / 100 / 332	0 / 130 / 986 / 3,901	0 / 130 / 5,266
Micro Sterility Suite	Floor site in doorway - room entrance.	0 / 59 / 16.00 / 64	0 / 100 / 18.00 / 60	0 / 100 / 21.00 / 68	0 / 100 / 192	0 / 100 / 22.00 / 62	0 / 100 / 17.00 / 57	0 / 100 / 17.00 / 68	0 / 57 / 16.00 / 66	0 / 100 / 20.00 / 62	0 / 100 / 15.00 / 66	1 / 100 / 20.00 / 64	0 / 100 / 20.00 / 65	0 / 100 / 20.00 / 48	0 / 100 / 558	0 / 100 / 750
	Floor site in front of laminar flow hood.	1 / 100 / 16.00 / 64	0 / 100 / 16.00 / 60	0 / 100 / 22.00 / 69	0 / 100 / 193	0 / 31 / 14.00 / 60	0 / 100 / 16.00 / 59	0 / 100 / 16.00 / 69	0 / 100 / 16.00 / 66	0 / 100 / 21.00 / 62	0 / 46 / 15.00 / 66	0 / 100 / 15.00 / 66	0 / 100 / 18.00 / 65	0 / 100 / 13.00 / 48	0 / 100 / 561	0 / 100 / 754
	Floor site in room corner - general cleanliness ass	0 / 100 / 18.00 / 64	0 / 100 / 18.00 / 63	0 / 100 / 20.00 / 66	0 / 100 / 193	0 / 100 / 18.00 / 62	0 / 56 / 14.00 / 59	1 / 100 / 20.00 / 69	0 / 100 / 17.00 / 65	0 / 57 / 16.00 / 63	0 / 100 / 17.00 / 64	0 / 100 / 21.00 / 66	0 / 100 / 17.00 / 64	0 / 100 / 20.00 / 46	0 / 100 / 558	0 / 100 / 751

CSSC Pharmaceuticals

Environmental Monitoring System

Facility: **EMS Test Facility**

Report Date: 10/21/99

12 Month Summary By Test Type

		1998				1999											Total
		10	11	12	Total	1	2	3	4	5	6	7	8	9	Total	
Micro Sterility Suite	Site on work surface of laminar flow hood.	0 / 100 / 11.00 / 66	0 / 100 / 11.00 / 60	0 / 100 / 15.00 / 66	0 / 100 / 192	0 / 100 / 13.00 / 62	0 / 100 / 14.00 / 58	0 / 31 / 10.00 / 68	0 / 100 / 15.00 / 65	0 / 100 / 13.00 / 62	0 / 100 / 16.00 / 65	0 / 100 / 13.00 / 65	0 / 21 / 9.00 / 66	0 / 100 / 11.00 / 47	0 / 100 / 558	0 / 100 / 750
	Total	258	243	269	0 / 100 / 202 / 770	246	233	274	262	249	261	261	260	189	0 / 100 / 585 / 2,235	3,005
Production Room 100 Hallway	Floor site near doorway to room 101.	6 / 100 / 52.00 / 4	1 / 45 / 26.00 / 4	33 / 47 / 40.00 / 5	1 / 100 / 13	14 / 35 / 21.00 / 3	37 / 43 / 39.00 / 3	16 / 44 / 29.00 / 5	25 / 43 / 34.00 / 4	4 / 15 / 11.00 / 4	6 / 47 / 31.00 / 5	21 / 42 / 32.00 / 4	11 / 36 / 23.00 / 3	28 / 50 / 43.00 / 4	4 / 50 / 35	1 / 100 / 48
	Floor site near doorway to room 102.	16 / 39 / 27.00 / 4	27 / 38 / 34.00 / 4	2 / 26 / 10.00 / 5	2 / 39 / 13	4 / 31 / 17.00 / 4	2 / 11 / 7.00 / 4	10 / 40 / 25.00 / 5	9 / 38 / 22.00 / 4	2 / 28 / 14.00 / 4	1 / 33 / 19.00 / 5	1 / 38 / 19.00 / 4	16 / 32 / 26.00 / 4	0 / 22 / 12.00 / 4	0 / 40 / 38	0 / 40 / 51
	Floor site near doorway to room 103.	12 / 100 / 37.00 / 4	2 / 40 / 20.00 / 4	1 / 39 / 23.00 / 5	1 / 100 / 13	0 / 47 / 20.00 / 4	3 / 67 / 30.00 / 4	12 / 33 / 21.00 / 5	4 / 100 / 34.00 / 4	7 / 19 / 14.00 / 3	14 / 37 / 25.00 / 5	6 / 21 / 11.00 / 4	23 / 38 / 30.00 / 4	13 / 37 / 24.00 / 3	0 / 100 / 36	0 / 100 / 49
	Floor site near doorway to room 104.	2 / 30 / 15.00 / 4	4 / 35 / 17.00 / 4	2 / 10 / 8.00 / 5	2 / 35 / 13	11 / 34 / 23.00 / 4	18 / 39 / 32.00 / 4	3 / 38 / 23.00 / 5	6 / 31 / 19.00 / 4	11 / 30 / 21.00 / 4	2 / 70 / 27.00 / 5	5 / 100 / 34.00 / 4	5 / 37 / 23.00 / 4	24 / 43 / 35.00 / 4	2 / 100 / 38	2 / 100 / 51
	Wall site near doorway to room 101.	3 / 37 / 16.00 / 4	30 / 56 / 44.00 / 3	2 / 29 / 11.00 / 4	2 / 56 / 11	0 / 88 / 39.00 / 4	5 / 90 / 45.00 / 4	11 / 43 / 22.00 / 4	11 / 43 / 24.00 / 4	2 / 100 / 41.00 / 4	12 / 40 / 26.00 / 5	7 / 30 / 18.00 / 3	8 / 100 / 58.00 / 4	0 / 45 / 28.00 / 3	0 / 100 / 35	0 / 100 / 46
	Wall site near doorway to room 102.	4 / 77 / 33.00 / 4	8 / 100 / 43.00 / 4	8 / 100 / 40.00 / 5	4 / 100 / 13	0 / 27 / 11.00 / 4	18 / 40 / 32.00 / 4	1 / 42 / 19.00 / 5	25 / 37 / 30.00 / 4	13 / 100 / 42.00 / 4	12 / 39 / 23.00 / 5	13 / 44 / 31.00 / 4	10 / 44 / 26.00 / 4	9 / 62 / 40.00 / 4	2 / 100 / 38	2 / 100 / 51
	Wall site near doorway to room 103.	2 / 23 / 11.00 / 4	1 / 43 / 17.00 / 4	1 / 42 / 15.00 / 5	1 / 43 / 13	6 / 41 / 28.00 / 4	3 / 9 / 7.00 / 3	19 / 40 / 31.00 / 5	15 / 37 / 25.00 / 4	1 / 30 / 14.00 / 4	17 / 36 / 24.00 / 5	9 / 42 / 30.00 / 4	16 / 50 / 39.00 / 4	0 / 44 / 21.00 / 4	0 / 50 / 37	0 / 50 / 50

Environmental Monitoring System

Facility: **EMS Test Facility**

Report Date: 10/21/99

		1998				1999										Total
		10	11	12	Total	1	2	3	4	5	6	7	8	9	Total	Total
Production Room 100 Hallway	Wall site near doorway to room 104.	2 / 72 / 30.00 / 3	0 / 33 / 17.00 / 4	6 / 41 / 24.00 / 5	0 / 72 / 12	22 / 100 / 63.00 / 4	0 / 32 / 18.00 / 4	0 / 42 / 14.00 / 5	2 / 80 / 28.00 / 3	6 / 43 / 19.00 / 4	5 / 33 / 15.00 / 5	3 / 26 / 16.00 / 4	13 / 42 / 32.00 / 4	20 / 44 / 33.00 / 4	0 / 100 / 37	0 / 100 / 49
	Total	2 / 100 / 31	0 / 100 / 31	1 / 100 / 39	0 / 100 / 608 / 101	0 / 100 / 31	0 / 90 / 30	0 / 44 / 39	2 / 100 / 31	1 / 100 / 31	1 / 70 / 40	1 / 100 / 31	5 / 100 / 31	0 / 62 / 30	0 / 100 / 1,877 / 294	0 / 100 / 395
Production Room 101 Gowning Area	Floor site in doorway - room entrance.	0 / 100 / 22.00 / 64	0 / 100 / 22.00 / 61	0 / 100 / 21.00 / 68	0 / 100 / 193	1 / 100 / 21.00 / 59	0 / 100 / 24.00 / 60	0 / 100 / 26.00 / 69	0 / 100 / 21.00 / 66	0 / 100 / 21.00 / 62	0 / 100 / 23.00 / 66	0 / 100 / 24.00 / 63	0 / 100 / 19.00 / 65	2 / 100 / 29.00 / 48	0 / 100 / 558	0 / 100 / 751
	Floor site in wash area near bench designating clas	0 / 50 / 16.00 / 65	0 / 100 / 19.00 / 63	0 / 100 / 19.00 / 67	0 / 100 / 195	0 / 100 / 19.00 / 62	0 / 100 / 19.00 / 60	0 / 100 / 21.00 / 68	0 / 100 / 20.00 / 65	0 / 100 / 18.00 / 62	1 / 100 / 19.00 / 64	0 / 100 / 18.00 / 66	0 / 100 / 19.00 / 66	0 / 100 / 22.00 / 45	0 / 100 / 558	0 / 100 / 753
	Floor site near door leading to controlled area.	0 / 100 / 14.00 / 65	1 / 100 / 17.00 / 63	0 / 100 / 20.00 / 69	0 / 100 / 197	0 / 49 / 16.00 / 61	1 / 100 / 16.00 / 56	0 / 37 / 13.00 / 69	0 / 100 / 13.00 / 63	0 / 44 / 15.00 / 61	1 / 100 / 19.00 / 62	0 / 45 / 14.00 / 65	0 / 100 / 16.00 / 66	0 / 100 / 16.00 / 47	0 / 100 / 550	0 / 100 / 747
	Floor site on clean side near bench designating clas	0 / 100 / 17.00 / 64	0 / 100 / 14.00 / 61	0 / 100 / 18.00 / 67	0 / 100 / 192	0 / 100 / 20.00 / 63	1 / 100 / 21.00 / 59	0 / 100 / 17.00 / 68	0 / 44 / 14.00 / 66	0 / 100 / 15.00 / 63	0 / 100 / 15.00 / 65	1 / 100 / 18.00 / 64	0 / 100 / 15.00 / 66	0 / 41 / 14.00 / 47	0 / 100 / 561	0 / 100 / 753
	Rodac sample on bench designating class transition a	0 / 100 / 19.00 / 66	0 / 100 / 18.00 / 63	0 / 100 / 23.00 / 68	0 / 100 / 197	0 / 100 / 20.00 / 61	0 / 55 / 18.00 / 58	0 / 59 / 18.00 / 68	0 / 100 / 20.00 / 65	0 / 100 / 18.00 / 62	1 / 100 / 18.00 / 64	0 / 53 / 17.00 / 64	0 / 100 / 17.00 / 64	1 / 44 / 17.00 / 47	0 / 100 / 553	0 / 100 / 750
	Wall site near door leading to controlled area.	1 / 100 / 18.00 / 66	0 / 100 / 15.00 / 60	0 / 100 / 18.00 / 67	0 / 100 / 193	0 / 100 / 17.00 / 63	0 / 100 / 17.00 / 57	0 / 41 / 14.00 / 68	0 / 100 / 19.00 / 65	0 / 100 / 18.00 / 61	1 / 100 / 17.00 / 66	0 / 100 / 16.00 / 66	0 / 37 / 13.00 / 64	0 / 100 / 17.00 / 47	0 / 100 / 557	0 / 100 / 750
	Wall site near doorway - room entrance.	1 / 100 / 26.00 / 64	2 / 100 / 28.00 / 62	0 / 100 / 26.00 / 66	0 / 100 / 192	0 / 100 / 26.00 / 62	0 / 100 / 27.00 / 59	0 / 100 / 25.00 / 68	1 / 100 / 23.00 / 64	0 / 100 / 23.00 / 62	0 / 100 / 28.00 / 60	0 / 100 / 25.00 / 66	0 / 100 / 23.00 / 64	0 / 100 / 27.00 / 44	0 / 100 / 549	0 / 100 / 741

CSSC Pharmaceuticals

Environmental Monitoring System

Facility: **EMS Test Facility**

Report Date: 10/21/99

		1998				1999											Total
		10	11	12	Total	1	2	3	4	5	6	7	8	9	Total	
Production Room 101 Gowning Area	Wall site near sink in wash area.	0 100 21.00 66	0 100 23.00 62	0 100 23.00 68	0 100 196	0 100 22.00 63	0 100 26.00 60	0 100 24.00 69	0 100 26.00 66	0 60 21.00 61	0 100 24.00 62	1 100 24.00 64	1 100 22.00 65	0 100 23.00 46	0 100 556	0 100 752
	Total	0 100 520	0 100 495	0 100 540	0 100 475 1,555	0 100 494	0 100 469	0 100 547	0 100 520	0 100 494	0 100 509	0 100 518	0 100 520	0 100 371	0 100 1,420 4,442	0 100 5,997
Production Room 102 Bottle Storage	Floor site in center of room.	3 33 17.00 4	12 100 43.00 4	0 25 14.00 5	0 100 13	7 35 23.00 4	7 61 33.00 4	4 38 23.00 5	1 29 16.00 4	17 37 29.00 4	2 30 15.00 5	0 36 16.00 4	4 43 26.00 4	0 41 18.00 4	0 61 38	0 100 51
	Floor site in corner of room.	4 37 23.00 3	3 33 20.00 4	2 100 38.00 5	2 100 12	7 29 19.00 3	10 38 25.00 4	12 33 23.00 5	5 17 11.00 4	6 32 19.00 4	18 40 31.00 5	14 28 20.00 4	7 100 51.00 4	0 100 42.00 4	0 100 37	0 100 49
	Floor site in doorway - room entrance.	13 51 29.00 4	7 34 21.00 4	0 37 9.00 5	0 51 13	6 37 24.00 4	3 50 27.00 4	2 36 18.00 5	28 100 71.00 4	11 36 23.00 4	4 100 39.00 5	20 38 29.00 4	11 75 34.00 4	7 39 27.00 3	2 100 37	0 100 50
	Wall site near doorway - room entrance.	3 25 16.00 4	2 100 34.00 4	15 63 32.00 5	2 100 13	1 22 10.00 4	12 40 19.00 4	7 19 14.00 5	10 35 25.00 3	3 23 13.00 4	11 37 26.00 5	4 16 10.00 4	7 25 13.00 4	2 30 12.00 3	1 40 36	1 100 49
	Wall site on near wall above stored bottles.	7 39 20.00 3	2 33 15.00 4	8 100 36.00 5	2 100 12	11 66 32.00 4	5 12 9.00 4	14 100 38.00 5	4 46 19.00 4	7 34 20.00 4	1 66 30.00 5	10 36 22.00 4	11 22 17.00 4	0 19 13.00 4	0 100 38	0 100 50
	Total	3 51 18	2 100 20	0 100 25	0 100 365 63	1 66 19	3 61 20	2 100 25	1 100 19	3 37 20	1 100 25	0 38 20	4 100 20	0 100 18	0 100 1,070 186	0 100 249
Production Room 103 Bottling	Floor site in center of room.	7 16 13.00 4	6 100 39.00 4	8 100 31.00 5	6 100 13	7 100 38.00 4	19 35 29.00 4	0 18 10.00 5	2 30 17.00 4	5 21 10.00 4	8 34 21.00 5	5 27 16.00 3	8 59 29.00 4	11 27 20.00 3	0 100 36	0 100 49

CSSC Pharmaceuticals

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Environmental Monitoring System

Facility: **EMS Test Facility**

Report Date: 10/21/99

Production Room 103 Bottling

Each cell lists values stacked as: count / percent / value / n

Site	1998 10	1998 11	1998 12	1998 Total	1999 1	1999 2	1999 3	1999 4	1999 5	1999 6	1999 7	1999 8	1999 9	1999 Total	Total
Floor site in doorway - room entrance.	2 / 18 / 9.00 / 4	15 / 43 / 27.00 / 4	4 / 100 / 33.00 / 5	2 / 100 / 13	14 / 26 / 18.00 / 4	3 / 33 / 19.00 / 3	3 / 41 / 20.00 / 5	0 / 100 / 34.00 / 4	18 / 100 / 41.00 / 4	13 / 32 / 23.00 / 4	2 / 100 / 47.00 / 4	18 / 26 / 21.00 / 4	0 / 100 / 31.00 / 4	0 / 100 / 36	0 / 100 / 49
Floor site near work surface.	7 / 20 / 15.00 / 4	5 / 38 / 20.00 / 4	1 / 49 / 20.00 / 5	1 / 49 / 13	1 / 21 / 9.00 / 4	13 / 24 / 18.00 / 4	7 / 61 / 22.00 / 5	0 / 35 / 17.00 / 4	5 / 58 / 25.00 / 4	6 / 34 / 17.00 / 5	1 / 28 / 12.00 / 4	3 / 21 / 13.00 / 3	10 / 32 / 23.00 / 4	0 / 61 / 37	0 / 61 / 50
Floor site within laminar flow curtains near bottling equipm	7 / 21 / 16.00 / 4	12 / 33 / 21.00 / 3	1 / 25 / 18.00 / 5	1 / 33 / 12	1 / 31 / 15.00 / 4	0 / 20 / 13.00 / 4	2 / 27 / 16.00 / 5	10 / 25 / 19.00 / 4	2 / 49 / 18.00 / 4	0 / 20 / 8.00 / 5	7 / 13 / 9.00 / 4	1 / 17 / 7.00 / 4	0 / 24 / 7.00 / 4	0 / 49 / 38	0 / 49 / 50
Rodac sample on bottling equipment within laminar fl	0 / 13 / 5.00 / 3	8 / 17 / 13.00 / 4	1 / 100 / 24.00 / 5	0 / 100 / 12	2 / 23 / 10.00 / 4	4 / 100 / 32.00 / 4	0 / 11 / 7.00 / 5	1 / 11 / 6.00 / 4	7 / 100 / 34.00 / 4	0 / 14 / 8.00 / 5	0 / 12 / 6.00 / 4	10 / 14 / 12.00 / 4	0 / 8 / 4.00 / 4	0 / 100 / 38	0 / 100 / 50
Rodac sample on door handle.	2 / 100 / 40.00 / 3	0 / 51 / 17.00 / 4	12 / 100 / 53.00 / 5	0 / 100 / 12	18 / 35 / 26.00 / 4	0 / 32 / 12.00 / 4	2 / 23 / 12.00 / 5	8 / 34 / 20.00 / 4	5 / 23 / 14.00 / 4	5 / 100 / 34.00 / 5	3 / 33 / 16.00 / 4	6 / 64 / 31.00 / 4	6 / 34 / 18.00 / 4	0 / 100 / 38	0 / 100 / 50
Wall site above countertop.	3 / 100 / 36.00 / 4	7 / 66 / 32.00 / 4	15 / 39 / 23.00 / 5	3 / 100 / 13	0 / 25 / 14.00 / 4	28 / 35 / 33.00 / 4	9 / 39 / 29.00 / 5	0 / 3 / 1.00 / 3	10 / 35 / 20.00 / 4	1 / 37 / 11.00 / 5	2 / 32 / 10.00 / 4	12 / 75 / 36.00 / 4	10 / 40 / 32.00 / 4	0 / 75 / 37	0 / 100 / 50
Wall site near laminar flow curtains.	1 / 40 / 18.00 / 4	6 / 31 / 15.00 / 4	2 / 35 / 19.00 / 5	1 / 40 / 13	5 / 34 / 24.00 / 3	2 / 40 / 18.00 / 4	4 / 31 / 15.00 / 5	6 / 37 / 22.00 / 4	10 / 61 / 27.00 / 4	3 / 31 / 22.00 / 5	6 / 28 / 17.00 / 3	7 / 40 / 28.00 / 4	18 / 100 / 45.00 / 4	2 / 100 / 36	1 / 100 / 49
Wall site on far wall near air return grate.	26 / 40 / 35.00 / 4	11 / 34 / 25.00 / 4	9 / 100 / 53.00 / 4	9 / 100 / 12	4 / 31 / 13.00 / 4	15 / 68 / 35.00 / 4	26 / 100 / 45.00 / 5	0 / 28 / 10.00 / 4	1 / 100 / 39.00 / 4	11 / 100 / 43.00 / 4	0 / 29 / 14.00 / 4	7 / 35 / 21.00 / 4	1 / 28 / 13.00 / 4	0 / 100 / 37	0 / 100 / 49
Total	0 / 100 / 34	0 / 100 / 35	1 / 100 / 44	0 / 100 / 668 / 113	0 / 100 / 35	0 / 100 / 35	0 / 100 / 45	0 / 100 / 35	1 / 100 / 36	0 / 100 / 43	0 / 100 / 34	1 / 75 / 35	0 / 100 / 35	0 / 100 / 1,648 / 333	0 / 100 / 446

Environmental Monitoring System

Facility: **EMS Test Facility**

Report Date: 10/21/99

Each data cell lists the stacked values as: count / % / value / n (Total columns list count / % / total).

Site	1998 10	1998 11	1998 12	1998 Total	1999 1	1999 2	1999 3	1999 4	1999 5	1999 6	1999 7	1999 8	1999 9	1999 Total	Total
Production Room 104 Capping															
Floor site between workstations near countertop.	2/29/16.00/4	5/22/14.00/4	5/26/16.00/5	2/29/13	4/29/17.00/4	7/24/14.00/4	1/26/13.00/5	17/28/24.00/4	0/24/11.00/4	4/26/14.00/5	6/59/28.00/4	12/26/19.00/4	0/100/32.00/4	0/100/38	0/100/51
Floor site in doorway - room entrance.	15/100/38.00/4	2/100/43.00/4	10/25/20.00/5	2/100/13	12/28/20.00/4	5/49/23.00/4	8/28/19.00/5	3/40/16.00/4	5/24/15.00/4	0/18/9.00/5	0/58/19.00/4	12/19/16.00/3	1/27/14.00/3	0/58/36	0/100/49
Floor site in room corner - general cleanliness ass	1/40/17.00/4	3/29/18.00/4	0/31/17.00/5	0/40/13	5/37/19.00/4	3/27/17.00/3	11/25/17.00/5	2/62/30.00/4	4/34/17.00/4	13/38/29.00/5	14/100/39.00/4	3/9/7.00/4	6/30/21.00/4	2/100/37	0/100/50
Floor site within laminar flow curtains near capper.	0/4/3.00/4	0/17/6.00/4	3/14/9.00/4	0/17/12	0/24/10.00/4	4/20/16.00/4	0/100/26.00/5	4/18/12.00/4	0/39/20.00/4	1/16/10.00/5	4/15/8.00/4	0/40/18.00/4	10/19/13.00/4	0/100/38	0/100/50
Rodac site on capping equipment within laminar fl	0/13/17.00/8	0/15/16.00/8	1/15/13.00/10	0/15/26	3/27/15.00/8	0/14/15.00/8	0/15/15.00/10	1/100/39.00/8	3/100/40.00/7	0/13/12.00/10	3/100/43.00/8	4/18/23.00/8	7/15/24.00/8	0/100/75	0/100/101
Rodac site on production surface.	10/15/12.00/4	2/45/21.00/3	4/24/14.00/5	2/45/12	1/26/11.00/4	10/22/16.00/4	12/18/14.00/5	14/100/39.00/4	2/15/9.00/4	0/23/9.00/5	3/21/15.00/4	10/21/15.00/4	8/25/14.00/4	0/100/38	0/100/50
Wall site on window near laminar flow curtains.	4/25/13.00/4	9/24/16.00/4	0/29/14.00/5	0/29/13	12/27/17.00/4	3/100/30.00/4	4/100/32.00/5	3/43/17.00/4	19/100/41.00/4	9/28/19.00/5	11/100/56.00/2	9/28/22.00/4	3/12/9.00/4	3/100/36	0/75/49
Total	0/100/32	0/100/31	0/31/39	0/100/354/102	0/37/32	0/100/31	0/100/40	1/100/32	0/100/31	0/38/40	0/100/30	0/40/31	0/100/31	0/100/1,258/298	0/100/400
Production Room 205 Raw Material Storage															
Floor site in center of room.	1/39/19.00/4	12/29/19.00/4	0/39/20.00/5	0/39/13	12/38/27.00/4	2/70/30.00/4	7/31/20.00/5	2/34/14.00/4	5/31/18.00/4	6/31/15.00/5	2/75/37.00/4	20/35/27.00/4	6/29/19.00/4	2/75/38	0/75/51

Environmental Monitoring System

Facility: **EMS Test Facility**

Report Date: 10/21/99

Location	Site	1998 10	1998 11	1998 12	1998 Total	1999 1	1999 2	1999 3	1999 4	1999 5	1999 6	1999 7	1999 8	1999 9	1999 Total	Total
Production Room 205 Raw Material Storage	Floor site near desk in corner of room.	5 / 23 / 14.00 / 4	2 / 25 / 14.00 / 3	5 / 32 / 23.00 / 5	2 / 32 / 12	1 / 28 / 16.00 / 4	2 / 36 / 23.00 / 3	26 / 42 / 32.00 / 5	17 / 34 / 25.00 / 4	5 / 100 / 38.00 / 4	16 / 36 / 25.00 / 5	3 / 29 / 14.00 / 4	8 / 25 / 21.00 / 4	4 / 35 / 17.00 / 4	1 / 100 / 37	1 / 100 / 49
	Floor site near doorway - room entrance.	13 / 35 / 25.00 / 4	8 / 39 / 18.00 / 4	12 / 40 / 24.00 / 4	8 / 40 / 12	19 / 40 / 33.00 / 4	0 / 15 / 6.00 / 4	0 / 64 / 22.00 / 5	6 / 32 / 21.00 / 4	8 / 40 / 22.00 / 4	6 / 28 / 18.00 / 5	5 / 39 / 19.00 / 4	11 / 40 / 25.00 / 4	8 / 100 / 44.00 / 3	0 / 100 / 37	0 / 100 / 49
	Wall site near doorway - room entrance.	26 / 47 / 38.00 / 4	13 / 82 / 43.00 / 4	31 / 100 / 47.00 / 5	13 / 100 / 13	5 / 42 / 17.00 / 4	5 / 32 / 22.00 / 4	5 / 39 / 21.00 / 5	26 / 46 / 34.00 / 4	1 / 31 / 19.00 / 4	6 / 39 / 27.00 / 5	20 / 47 / 32.00 / 4	33 / 49 / 39.00 / 4	0 / 34 / 13.00 / 4	0 / 49 / 38	0 / 100 / 51
	Wall site near stored raw materials.	6 / 32 / 15.00 / 4	33 / 37 / 36.00 / 4	6 / 32 / 21.00 / 5	6 / 37 / 13	6 / 39 / 22.00 / 4	11 / 39 / 23.00 / 4	4 / 34 / 20.00 / 5	4 / 100 / 34.00 / 4	2 / 16 / 8.00 / 4	7 / 39 / 31.00 / 5	3 / 31 / 11.00 / 4	12 / 100 / 37.00 / 4	14 / 38 / 21.00 / 4	2 / 100 / 38	2 / 100 / 51
	Total	1 / 47 / 20	2 / 82 / 19	0 / 100 / 24	0 / 100 / 376 / 63	1 / 42 / 20	0 / 70 / 19	0 / 64 / 25	2 / 100 / 20	1 / 100 / 20	6 / 39 / 25	2 / 75 / 20	8 / 100 / 20	0 / 100 / 19	0 / 100 / 1,054 / 188	0 / 100 / 251
Production Room 206 Personnel Prep Area	Floor site near doorway - room entrance.	0 / 100 / 14.00 / 66	0 / 100 / 16.00 / 66	0 / 48 / 17.00 / 72	0 / 100 / 204	0 / 48 / 16.00 / 66	0 / 100 / 18.00 / 63	0 / 100 / 15.00 / 70	0 / 45 / 13.00 / 68	0 / 100 / 14.00 / 65	0 / 100 / 15.00 / 71	0 / 100 / 17.00 / 69	0 / 100 / 17.00 / 70	0 / 100 / 16.00 / 52	0 / 100 / 594	0 / 100 / 798
	Floor site near lockers and bench.	0 / 100 / 25.00 / 70	0 / 100 / 24.00 / 66	0 / 100 / 25.00 / 72	0 / 100 / 208	2 / 59 / 20.00 / 67	0 / 78 / 25.00 / 63	1 / 100 / 26.00 / 71	0 / 100 / 25.00 / 69	0 / 100 / 24.00 / 66	0 / 100 / 26.00 / 70	0 / 100 / 24.00 / 70	0 / 100 / 27.00 / 70	0 / 57 / 21.00 / 52	0 / 100 / 598	0 / 100 / 806
	Floor site near sinks 1 and 2.	3 / 22 / 14.00 / 4	8 / 21 / 15.00 / 4	9 / 36 / 25.00 / 5	3 / 36 / 13	0 / 33 / 13.00 / 4	16 / 34 / 25.00 / 4	0 / 34 / 13.00 / 5	0 / 36 / 21.00 / 3	5 / 52 / 24.00 / 4	7 / 58 / 28.00 / 5	12 / 37 / 28.00 / 4	19 / 32 / 26.00 / 4	6 / 38 / 21.00 / 4	0 / 58 / 37	0 / 58 / 50
	Floor site near sinks 2 and 3.	2 / 100 / 30.00 / 4	4 / 40 / 25.00 / 4	0 / 26 / 14.00 / 5	0 / 100 / 13	19 / 69 / 37.00 / 4	0 / 100 / 35.00 / 4	0 / 24 / 10.00 / 5	3 / 21 / 13.00 / 4	10 / 35 / 23.00 / 4	6 / 100 / 32.00 / 5	17 / 54 / 32.00 / 4	10 / 100 / 38.00 / 4	4 / 18 / 13.00 / 4	0 / 100 / 38	0 / 100 / 51

CSSC Pharmaceuticals

Environmental Monitoring System

Facility: **EMS Test Facility**

Report Date: 10/21/99

12 Month Summary By Test Type

Site	1998 10	1998 11	1998 12	1998 Total	1999 1	1999 2	1999 3	1999 4	1999 5	1999 6	1999 7	1999 8	1999 9	1999 Total	Total
Production Room 206 Personnel Prep Area															
Wall site near doorway - room entrance.	15 / 44 / 29.00 / 4	3 / 24 / 10.00 / 4	12 / 99 / 40.00 / 5	3 / 99 / 13	15 / 37 / 22.00 / 4	5 / 14 / 10.00 / 4	5 / 40 / 20.00 / 5	22 / 73 / 41.00 / 4	10 / 28 / 17.00 / 3	19 / 100 / 43.00 / 5	10 / 42 / 31.00 / 4	10 / 42 / 19.00 / 4	13 / 41 / 21.00 / 4	5 / 100 / 37	3 / 100 / 50
Wall site near lockers.	3 / 38 / 20.00 / 4	6 / 46 / 28.00 / 4	3 / 79 / 37.00 / 5	3 / 79 / 13	11 / 48 / 31.00 / 4	24 / 42 / 32.00 / 4	31 / 50 / 42.00 / 5	31 / 68 / 48.00 / 4	15 / 44 / 29.00 / 4	0 / 38 / 15.00 / 5	29 / 46 / 34.00 / 4	7 / 39 / 23.00 / 4	11 / 42 / 22.00 / 4	0 / 68 / 38	0 / 79 / 51
Wall site near sink 3.	0 / 99 / 29.00 / 68	2 / 52 / 27.00 / 66	1 / 100 / 29.00 / 73	0 / 100 / 207	0 / 100 / 31.00 / 65	0 / 100 / 25.00 / 64	0 / 100 / 31.00 / 74	0 / 100 / 33.00 / 69	2 / 100 / 26.00 / 67	0 / 100 / 34.00 / 70	0 / 100 / 29.00 / 68	0 / 100 / 30.00 / 67	1 / 100 / 32.00 / 50	0 / 100 / 594	0 / 100 / 801
Total	0 / 100 / 220	0 / 100 / 214	0 / 100 / 237	0 / 100 / 491 / 671	0 / 100 / 214	0 / 100 / 206	0 / 100 / 235	0 / 100 / 221	0 / 100 / 213	0 / 100 / 231	0 / 100 / 223	0 / 100 / 223	0 / 100 / 170	0 / 100 / 1,559 / 1,936	0 / 100 / 2,607
Production Room 207 Tablet Milling															
Floor site in center of room.	1 / 34 / 18.00 / 4	2 / 33 / 17.00 / 4	5 / 30 / 22.00 / 5	1 / 34 / 13	4 / 35 / 22.00 / 4	11 / 57 / 30.00 / 4	5 / 65 / 25.00 / 4	2 / 54 / 25.00 / 4	15 / 32 / 24.00 / 4	4 / 100 / 36.00 / 5	18 / 28 / 22.00 / 4	15 / 34 / 23.00 / 4	3 / 23 / 12.00 / 4	2 / 100 / 37	1 / 100 / 50
Floor site near doorway - room entrance.	14 / 65 / 33.00 / 4	12 / 17 / 14.00 / 4	5 / 34 / 20.00 / 5	5 / 65 / 13	0 / 32 / 23.00 / 4	3 / 30 / 15.00 / 4	0 / 35 / 15.00 / 5	13 / 58 / 30.00 / 4	0 / 33 / 11.00 / 4	0 / 34 / 12.00 / 5	16 / 35 / 25.00 / 4	9 / 30 / 17.00 / 4	3 / 20 / 10.00 / 4	0 / 58 / 38	0 / 65 / 51
Floor site near work surface.	4 / 43 / 25.00 / 4	20 / 34 / 29.00 / 3	4 / 100 / 40.00 / 5	4 / 100 / 12	1 / 19 / 10.00 / 4	8 / 40 / 26.00 / 4	8 / 31 / 13.00 / 5	8 / 35 / 26.00 / 4	1 / 20 / 13.00 / 4	8 / 22 / 15.00 / 4	4 / 33 / 13.00 / 4	3 / 33 / 17.00 / 4	17 / 33 / 24.00 / 3	0 / 40 / 36	0 / 100 / 48
Floor site within laminar flow curtains near tablet miller.	0 / 21 / 11.00 / 4	0 / 25 / 14.00 / 4	0 / 14 / 8.00 / 5	0 / 25 / 13	5 / 15 / 11.00 / 4	23 / 25 / 24.00 / 4	1 / 36 / 16.00 / 5	9 / 25 / 19.00 / 4	12 / 40 / 27.00 / 4	1 / 25 / 6.00 / 5	9 / 25 / 18.00 / 4	7 / 28 / 17.00 / 4	2 / 32 / 14.00 / 4	1 / 40 / 38	0 / 40 / 51
Wall site near doorway - room entrance.	19 / 31 / 26.00 / 4	2 / 22 / 14.00 / 4	4 / 48 / 21.00 / 5	2 / 48 / 13	11 / 43 / 26.00 / 4	0 / 20 / 8.00 / 3	3 / 29 / 16.00 / 5	2 / 24 / 10.00 / 4	4 / 100 / 44.00 / 3	11 / 47 / 24.00 / 5	0 / 30 / 15.00 / 4	3 / 14 / 10.00 / 4	1 / 26 / 14.00 / 4	0 / 100 / 36	0 / 100 / 49

CSSC Pharmaceuticals

Environm ntal Monitoring System

Facility: **EMS Test Facility**

Report Date: 10/21/99

12 Month Summary By Test Type

	1998 10	1998 11	1998 12	1998 Total	1999 1	1999 2	1999 3	1999 4	1999 5	1999 6	1999 7	1999 8	1999 9	1999 Total	Total
Production Room 207 Tablet Milling — Total	0 / 65 / 20	0 / 34 / 19	0 / 100 / 25	0 / 100 / 310 / 64	0 / 43 / 20	0 / 57 / 19	0 / 65 / 24	2 / 58 / 20	0 / 100 / 19	0 / 100 / 24	0 / 35 / 20	3 / 34 / 20	1 / 33 / 19	0 / 100 / 853 / 185	0 / 100 / 249
Production Room 208 Packaging — Floor site in center of room.	7 / 29 / 18.00 / 4	38 / 100 / 55.00 / 4	4 / 25 / 9.00 / 5	4 / 100 / 13	10 / 35 / 25.00 / 4	12 / 39 / 23.00 / 4	4 / 34 / 17.00 / 5	17 / 100 / 43.00 / 4	2 / 26 / 16.00 / 4	15 / 36 / 25.00 / 5	2 / 23 / 11.00 / 4	6 / 40 / 22.00 / 4	5 / 38 / 17.00 / 4	2 / 100 / 38	2 / 100 / 51
Floor site near boxing equipment.	11 / 63 / 30.00 / 4	1 / 24 / 11.00 / 4	3 / 29 / 14.00 / 5	1 / 63 / 13	3 / 31 / 16.00 / 4	9 / 100 / 45.00 / 4	11 / 33 / 20.00 / 5	13 / 33 / 20.00 / 4	4 / 53 / 26.00 / 3	0 / 34 / 15.00 / 5	3 / 55 / 33.00 / 4	5 / 40 / 21.00 / 4	1 / 24 / 11.00 / 4	0 / 100 / 37	0 / 100 / 50
Floor site near doorway - room entrance.	26 / 80 / 52.00 / 4	1 / 16 / 9.00 / 4	2 / 36 / 21.00 / 5	1 / 80 / 13	15 / 38 / 22.00 / 4	4 / 36 / 22.00 / 3	4 / 50 / 26.00 / 5	13 / 37 / 25.00 / 4	3 / 26 / 17.00 / 4	5 / 65 / 21.00 / 5	2 / 19 / 9.00 / 3	11 / 61 / 40.00 / 4	7 / 34 / 24.00 / 4	2 / 65 / 36	1 / 80 / 49
Floor site near sink.	8 / 34 / 19.00 / 4	18 / 100 / 42.00 / 4	6 / 54 / 19.00 / 5	6 / 100 / 13	21 / 34 / 28.00 / 4	4 / 41 / 27.00 / 4	1 / 100 / 31.00 / 4	8 / 37 / 18.00 / 4	15 / 44 / 24.00 / 4	16 / 31 / 24.00 / 4	6 / 31 / 19.00 / 4	13 / 35 / 20.00 / 4	0 / 35 / 21.00 / 4	0 / 100 / 37	0 / 100 / 50
Rodac site on boxing equipment.	2 / 31 / 10.00 / 4	8 / 37 / 20.00 / 4	8 / 33 / 24.00 / 5	2 / 37 / 13	13 / 80 / 39.00 / 4	1 / 100 / 27.00 / 4	12 / 32 / 25.00 / 5	10 / 54 / 23.00 / 4	4 / 59 / 25.00 / 3	2 / 29 / 16.00 / 5	8 / 37 / 22.00 / 4	19 / 100 / 43.00 / 4	14 / 48 / 27.00 / 4	1 / 100 / 37	1 / 100 / 50
Wall site near boxing equipment.	7 / 41 / 23.00 / 4	1 / 100 / 35.00 / 4	0 / 32 / 13.00 / 5	0 / 100 / 13	2 / 25 / 15.00 / 4	7 / 47 / 25.00 / 4	2 / 33 / 13.00 / 5	13 / 73 / 34.00 / 4	4 / 58 / 30.00 / 4	9 / 90 / 33.00 / 5	8 / 34 / 18.00 / 4	0 / 100 / 38.00 / 4	6 / 56 / 32.00 / 4	0 / 100 / 38	0 / 100 / 51
Wall site near doorway - room entrance.	0 / 100 / 38.00 / 4	16 / 34 / 25.00 / 4	0 / 42 / 19.00 / 5	0 / 100 / 13	16 / 30 / 25.00 / 4	11 / 35 / 17.00 / 4	15 / 43 / 26.00 / 5	14 / 65 / 35.00 / 4	1 / 21 / 11.00 / 4	29 / 53 / 37.00 / 5	3 / 78 / 26.00 / 4	3 / 38 / 18.00 / 3	13 / 34 / 24.00 / 4	1 / 78 / 37	0 / 100 / 50
Total	0 / 100 / 28	1 / 100 / 28	0 / 54 / 35	0 / 100 / 503 / 91	2 / 80 / 28	1 / 100 / 27	1 / 100 / 35	8 / 100 / 28	1 / 59 / 26	0 / 90 / 34	2 / 78 / 27	0 / 100 / 27	0 / 56 / 28	0 / 100 / 1,524 / 260	0 / 100 / 351

Environmental Monitoring System

Facility: **EMS Test Facility**

Report Date: 10/21/99

12 Month Summary By Test Type

Production Room 209 Lyophilization

Site	1998 10	1998 11	1998 12	1998 Total	1999 1	1999 2	1999 3	1999 4	1999 5	1999 6	1999 7	1999 8	1999 9	1999 Total	Total
Equipment site on the door of lyophilizer 1.	0 / 100 / 9.00 / 69	0 / 100 / 10.00 / 67	0 / 100 / 13.00 / 73	0 / 100 / 209	0 / 15 / 8.00 / 67	0 / 100 / 13.00 / 63	0 / 100 / 11.00 / 71	0 / 100 / 12.00 / 68	0 / 100 / 9.00 / 67	0 / 100 / 11.00 / 70	0 / 26 / 7.00 / 68	0 / 100 / 12.00 / 69	0 / 100 / 10.00 / 52	0 / 100 / 595	0 / 100 / 804
Equipment site on the door of lyophilizer 2.	0 / 100 / 11.00 / 68	0 / 100 / 10.00 / 65	0 / 100 / 15.00 / 73	0 / 100 / 206	0 / 100 / 14.00 / 67	0 / 100 / 10.00 / 64	0 / 100 / 10.00 / 74	0 / 100 / 10.00 / 68	0 / 100 / 12.00 / 67	0 / 100 / 12.00 / 70	0 / 100 / 11.00 / 69	0 / 100 / 10.00 / 68	0 / 100 / 12.00 / 51	0 / 100 / 598	0 / 100 / 804
Equipment site on the door of lyophilizer 3.	0 / 100 / 10.00 / 69	0 / 100 / 15.00 / 66	0 / 100 / 11.00 / 73	0 / 100 / 208	0 / 100 / 12.00 / 65	0 / 100 / 11.00 / 61	0 / 100 / 11.00 / 71	0 / 100 / 12.00 / 68	0 / 100 / 9.00 / 64	0 / 100 / 10.00 / 71	1 / 100 / 14.00 / 69	0 / 100 / 12.00 / 68	0 / 100 / 12.00 / 51	0 / 100 / 588	0 / 100 / 796
Floor site in center of room.	0 / 100 / 15.00 / 69	0 / 100 / 17.00 / 64	0 / 100 / 17.00 / 74	0 / 100 / 207	3 / 100 / 18.00 / 66	0 / 100 / 20.00 / 63	0 / 100 / 18.00 / 71	0 / 100 / 17.00 / 70	0 / 100 / 16.00 / 67	0 / 100 / 22.00 / 69	0 / 100 / 16.00 / 68	0 / 100 / 20.00 / 70	0 / 100 / 18.00 / 52	0 / 100 / 596	0 / 100 / 803
Floor site near work surface.	0 / 46 / 14.00 / 69	0 / 100 / 15.00 / 66	0 / 100 / 16.00 / 73	0 / 100 / 208	0 / 100 / 18.00 / 67	0 / 100 / 18.00 / 63	0 / 100 / 18.00 / 74	0 / 100 / 17.00 / 67	0 / 40 / 14.00 / 67	0 / 100 / 16.00 / 71	0 / 100 / 16.00 / 70	0 / 100 / 18.00 / 69	0 / 39 / 15.00 / 51	0 / 100 / 599	0 / 100 / 807
Floor site within laminar flow curtains between lyophili	0 / 100 / 14.00 / 69	0 / 100 / 13.00 / 66	0 / 100 / 15.00 / 70	0 / 100 / 205	0 / 40 / 11.00 / 64	0 / 30 / 12.00 / 63	0 / 100 / 12.00 / 72	0 / 100 / 13.00 / 69	0 / 100 / 14.00 / 66	0 / 100 / 16.00 / 70	0 / 39 / 11.00 / 67	0 / 100 / 11.00 / 70	0 / 100 / 11.00 / 52	0 / 100 / 593	0 / 100 / 798
Floor site within laminar flow curtains between lyophili	0 / 100 / 11.00 / 70	0 / 100 / 12.00 / 66	0 / 100 / 14.00 / 71	0 / 100 / 207	0 / 100 / 12.00 / 66	0 / 100 / 18.00 / 63	0 / 100 / 12.00 / 73	0 / 100 / 17.00 / 67	0 / 100 / 13.00 / 64	1 / 100 / 13.00 / 71	0 / 38 / 11.00 / 70	0 / 40 / 10.00 / 69	0 / 100 / 14.00 / 51	0 / 100 / 594	0 / 100 / 801
Wall site above work surface.	0 / 100 / 19.00 / 69	0 / 100 / 21.00 / 65	0 / 100 / 22.00 / 74	0 / 100 / 208	0 / 51 / 16.00 / 63	0 / 100 / 15.00 / 63	3 / 100 / 20.00 / 70	0 / 100 / 22.00 / 69	0 / 100 / 21.00 / 66	0 / 100 / 21.00 / 69	0 / 100 / 21.00 / 68	0 / 100 / 23.00 / 68	1 / 100 / 24.00 / 51	0 / 100 / 587	0 / 100 / 795
Wall site near doorway - room entrance.	0 / 50 / 18.00 / 67	0 / 100 / 25.00 / 67	0 / 100 / 17.00 / 71	0 / 100 / 205	0 / 100 / 21.00 / 65	0 / 100 / 23.00 / 63	0 / 100 / 18.00 / 72	1 / 100 / 23.00 / 70	0 / 33 / 17.00 / 65	1 / 100 / 19.00 / 71	0 / 100 / 17.00 / 69	0 / 100 / 18.00 / 67	0 / 100 / 20.00 / 51	0 / 100 / 593	0 / 100 / 798

CSSC Pharmaceuticals

Environmental Monitoring System

Facility: **EMS   Test Facility**

Report Date: 10/21/99

12 Month Summary By Test Type

		1998				1999										Total
	Total	10	11	12	Total	1	2	3	4	5	6	7	8	9	Total	
Production Room 209 Lyophilizzation		0 100 619	0 100 592	0 100 652	0 100 398 1,863	0 100 590	0 100 566	0 100 648	0 100 616	0 100 593	0 100 632	0 100 618	0 100 618	0 100 462	0 100 1,198 5,343	0 100 7,206
Total																

CSSC Pharmaceuticals

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Room: Production Room 209 Lyophilization
Test Site: Equipment site on the door of lyophilizer 1.

Site Test Readings

Legend:
- Data
- Trend
- Avg
- ◇ MaxAlert
- ◆ MaxAction

Histogram

Room: Micro Sterility Suite
Test Site: Particulate count taken in room center.

Site Test Readings

Histogram

Micro Sterility Suite
Particulate count taken in room center.
Test Site Readings

Legend:
— Data
— Trend
— Avg
◇ MaxAlert
◆ MaxAction

X-axis: 10/01/98 11/05/98 12/15/98 01/21/99 03/02/99 04/12/99 05/19/99 06/25/99 08/04/99 09/13/99

Y-axis: 0 1 2 3 4 5 6 7 8 9 10

Room: Micro Sterility Suite
Test Site: Touch plate taken within laminar flow hood.

Company Name

Micro Sterility Suite
Touch plate taken within laminar flow hood.
Test Site Readings

Environmental Monitoring System

Survey Results

Report Date: 4/3/2000

Facility: **EMS Test Facility**
Group: **Daily Tests**

Survey Contol No.: 2069

Survey Date:	3/6/00
Survey Shift:	1

Product: **sqd**
Lot #: **xdwx**

Room ID: 6   RefNo   **MicroSterility**

Room Description
Micro Sterility Suite

Rodac TSA Plate

Test ID Ref	Test ID	Test Site Description	Sample Date / Sample By / Media Lot	Test Date / Test By / Equipment ID	Result Date / Result By	Sample ID / Room Activity	Result / Exception	Entry By / Enter Date
E1	41	Site on work surface of laminar flow hood.	3/6/00 7:23AM TNucci 1234R01	3/6/00 7:23AM TNucci None	3/13/00 9:10AM VGalliani	+S05146A Operational	1	lradigan 3/22/00 10:27PM
F1	38	Floor site in front of laminar flow hood.	3/6/00 7:05AM TNucci 1234R014	3/6/00 7:05AM TNucci None	3/13/00 8:00AM JRadigan	+S05143A Operational	18	lradigan 3/22/00 10:27PM
F2	39	Floor site in doorway - room entrance.	3/6/00 7:15AM TNucci 1234R01	3/6/00 7:15AM TNucci None	3/13/00 9:00AM TJoyce	+S05144A Operational	22	lradigan 3/22/00 10:27PM
F3	40	Floor site in room corner - general cleanliness assessment.	3/6/00 7:22AM TNucci 1234R01	3/6/00 7:22AM TNucci None	3/13/00 9:05AM TJoyce	+S05145A Operational	8	lradigan 3/22/00 10:27PM

Print #: 0

Reviewed By: _____   Date: _____

CSSC Pharmaceuticals

C:\EMS214\reports\SurveyResults.rpt

Environmental Monitoring System

Survey Results

Report Date: 4/3/2000

Facility: **EMS Test Facility**
Group: **Daily Tests**

Survey Contol No.: 2069

Survey Date: 3/6/00
Survey Shift: 1

Product: **sqd**
Lot #: **xdwx**

Room ID: 6   RefNo   **MicroSterility**

Room Description
Micro Sterility Suite

Non Viable Particulate

Test ID Ref	Test ID	Test Site Description	Sample Date / Sample By / Media Lot	Test Date / Test By / Equipment ID	Result Date / Result By	Sample ID / Room Activity	Result / Exception	Entry By / Enter Date
P1	45	Particulate count taken in room center.	3/6/00 7:15AM / JRadigan / None	3/6/00 7:15AM / JRadigan / 123444	3/6/00 7:15AM / JRadigan	+S05149A / Operational	1	iradigan / 3/22/00 11:15PM

Touch Plate

Test ID Ref	Test ID	Test Site Description	Sample Date / Sample By / Media Lot	Test Date / Test By / Equipment ID	Result Date / Result By	Sample ID / Room Activity	Result / Exception / Employee ID	Entry By / Enter Date
GeorgeL	42	Touch plate taken within laminar flow hood.	3/6/00 9:25AM / TNucci / 1234R01	3/6/00 9:25AM / TNucci	3/13/00 10:00AM / JRadigan	+S05147A / Operational	2 / GeorgeL	jradigan / 3/22/00 11:18PM
RLindsay	42	Touch plate taken within laminar flow hood.	3/6/00 9:26AM / TNucci / 1234R01	3/6/00 9:26AM / TNucci	3/13/00 10:00AM / RLindsay	+S05147B / Operational	2 / RLindsay	iradigan / 3/22/00 11:18PM

STA Plate

Test ID Ref	Test ID	Test Site Description	Sample Date / Sample By / Media Lot	Test Date / Test By / Equipment ID	Result Date / Result By	Sample ID / Room Activity	Result / Exception	Entry By / Enter Date
1	44	STA airborne contamination sample taken in room center.	3/6/00 10:25AM / TestQATech / 1234R01	3/6/00 10:25AM / TestQATech / None	3/11/00 11:00AM / VGalliani	+S05148A / Operational	3	iradigan / 3/22/00 11:18PM

Print #: 0

Reviewed By: _____   Date: _____

CSSC Pharmaceuticals

Environmental Monitoring System

Survey Results

Report Date: 4/3/2000

Facility: **EMS Test Facility**
Group: **Daily Tests**

Survey Contol No. 2069

Survey Date:	3/6/00
Survey Shift:	1

Product: **sqd**
Lot #: **xdwx**

Room ID: 6   RefNo   **MicroSterility**

Room Description
Micro Sterility Suite

Water pH

Test ID Ref	Test ID	Test Site Description	Sample Date / Sample By / Media Lot	Test Date / Test By / Equipment ID	Result Date / Result By	Sample ID / Room Activit)	Result / Exception	Entry By / Enter Date
WFI-000-1	1432	Point Of Use site at WFI Drop	3/6/00 1:30PM TNucci None	3/6/00 1:30PM TNucci None	3/6/00 2:50PM TJoyce	+S05150A Operational	6.3	iradigan 3/22/00 11:18PM

Print #:   0

Reviewed By: _____   Date: _____

CSSC Pharmaceuticals

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C:\EMS214\reports\SurveyResults.rpt

Environmental Monitoring System

Survey Results

Report Date: 4/3/2000

Facility: **EMS Test Facility**
Group: **Daily Tests**

Survey Contol No. **2069**

Survey Date:	3/6/00	Product: **sqd**
Survey Shift:	1	Lot #: **xdwx**

Room ID: 7   RefNo   **MicroGowning**

Room Description
Micro Gowning Area

RCS Air Sample

Test ID Ref	Test ID	Test Site Description	Sample Date / Sample By / Media Lot	Test Date / Test By / Equipment ID	Result Date / Result By	Sample ID / Room Activity	Result / Exception	Entry By / Enter Date
R1	34	RCS airborne contamination sample taken in center of wash area.	3/6/00 10:00AM TNucci None	3/6/00 10:00AM TNucci None	3/11/00 10:00AM JRadigan	+S05139A Operational	2	iradigan 3/22/00 11:18PM
R2	35	RCS airborne contamination sample taken in center of clean area.	3/6/00 11:00AM TNucci 1234	3/6/00 11:00AM TNucci Q232	3/11/00 1:50PM JRadigan	+S05140A Operational	2	iradigan 3/22/00 11:18PM

Non Viable Particulate

Test ID Ref	Test ID	Test Site Description	Sample Date / Sample By / Media Lot	Test Date / Test By / Equipment ID	Result Date / Result By	Sample ID / Room Activity	Result / Exception	Entry By / Enter Date
P1	36	Particulate count taken in center of wash area.	3/6/00 8:00AM TNucci	3/6/00 8:00AM TNucci None	3/6/00 8:00AM TNucci	+S05141A Operational	4 **Alert**	iradigan 3/22/00 10:01PM
P2	37	Particulate count taken in center of clean area.	3/6/00 8:05AM TNucci	3/6/00 8:05AM TNucci None	3/6/00 8:05AM TNucci	+S05142A Operational	1	iradigan 3/22/00 10:01PM

Print #: 0

Reviewed By: _____   Date: _____

CSSC Pharmaceuticals

Environmental Monitoring System

Survey Results

Report Date: 4/3/2000

Facility: **EMS Test Facility**
Group: **Daily Tests**

Survey Contol No. 2069

Product:	**sqd**
Lot #:	**xdwx**

Survey Date: 3/6/00
Survey Shift: 1

Room ID: 7   RefNo   **MicroGowning**

Room Description
Micro Gowning Area

Surface Swab

Test ID Ref	Test ID	Test Site Description	Sample Date / Sample By / Media Lot	Test Date / Test By / Equipment ID	Result Date / Result By	Sample ID / Room Activity	Result / Exception	Entry By / Enter Date
S1	32	Swab sample within sink 1.	3/6/00 8:55AM TNucci 11111111	3/6/00 8:55AM TNucci	3/13/00 1:15PM RWatson	**+S05137A** Operational	9	iradigan 3/22/00 11:18PM
		- tt4hrthrth - 22222222222 - Reason #3						
S2	33	Swab sample within sink 2.	3/6/00 8:56AM TNucci 11111111	3/6/00 8:56AM TNucci	3/13/00 2:30PM RLindsav	**+S05138A** Operational	2	iradigan 3/22/00 11:18PM

Print #: 0

Reviewed By: _____   Date: _____

CSSC Pharmaceuticals

Environmental Monitoring System

Report Date: 4/3/2000

Facility: **EMS Test Facility**
Group: **Daily Tests**

Survey Contol No. **2069**

Product: **sqd**
Lot #: **xdwx**

Survey Date: 3/6/00
Survey Shift: 1

Room ID: 74   RefNo   **Water System**   Room Description **Water System**

Water Endotoxin EU/ml

Test ID Ref	Test ID	Test Site Description	Sample Date / Sample By / Media Lot	Test Date / Test By / Equipment ID	Result Date / Result By	Sample ID / Room Activity)	Result / Exception	Entry By / Enter Date
D1LAL1	1433	Water Endotoxin at Drop 1 in Production Room A	3/6/00 8:23AM / TNucci	3/6/00 11:05AM / GeorgeL / 1234	3/6/00 1:35PM / TJoyce	+S05151A / Operational	5.200	iradigan / 3/22/00 11:18PM
D3LAL3	1435	Water Endotoxin test at Drop 3 in Production Prep Room	3/6/00 8:24AM / TNucci	3/6/00 9:25AM / GeorgeL / 1234	3/6/00 1:35PM / TJoyce	+S05152A / Operational	0.530	iradigan / 3/22/00 11:18PM

Water pH

Test ID Ref	Test ID	Test Site Description	Sample Date / Sample By / Media Lot	Test Date / Test By / Equipment ID	Result Date / Result By	Sample ID / Room Activity)	Result / Exception	Entry By / Enter Date
D1PH1	1436	Water pH at Drop 1 in Production Room A	3/6/00 10:05AM / TNucci / 12345R	3/6/00 10:05AM / TNucci / M-002	3/6/00 4:30PM / TJoyce	+S05153A / Operational	<0.8	iradigan / 3/22/00 11:18PM
		Yes						
D3PH3	1438	Water pH at Drop 3 in Production Prep Room	3/6/00 10:07AM / TNucci / 12345R	3/6/00 10:07AM / TNucci / M-002	3/6/00 4:25PM / TJoyce	+S05154A / Operational	4.6	jradigan / 3/22/00 11:18PM

Print #:   0

Reviewed By: _____   Date: _____

CSSC Pharmaceuticals

Environmental Monitoring System

Report Date: 4/3/2000

Facility: **EMS Test Facility**
Group: **Daily Tests**

Survey Contol No. 2069

Survey Date: 3/6/00
Survey Shift: 1

Product: **sqd**
Lot #: **xdwx**

Room ID: 74   RefNo **Water System**

Room Description
Water System

Water Conductivity

Test ID Ref	Test ID	Test Site Description	Sample Date / Sample By / Media/Lot	Test Date / Test By / Equipment ID	Result Date / Result By	Sample ID / Room Activity	Result / Exception	Entry By / Enter Date
WFI=003-02	1443	Water Conductivity	3/6/00 10:45AM TNucci	3/6/00 10:45AM TNucci M-002	3/6/00 10:45AM TNucci	+S05155A Operational	>4.5	iradigan 3/22/00 11:18PM
		NQ Reason						

Print #: 0

Reviewed By: _____ Date: _____

CSSC Pharmaceuticals

T st ID	3	Floor between workstations approx 2 feet in front of work table.							
Test ID User Ref	**02**		Test Type	**Rodac TSA Plate**			Site Type	**Floor**	
Room ID	**5 Micro Lab2 A174**								

Survey#	Test Date	Shift	Test By	SampleID	Room Activity	Read Date	Read By	Reading	TNTC	NoTest	Rslt Status
1003	6/16/99	1	JRadigan	S-00490	Normal	1/25/99	TJoyce	0	N	N	**OK**
1005	7/12/99	1	JRadigan	S-00790	Normal	2/6/99	TJoyce	0	N	N	**OK**
1030	1/25/99	3	JRadigan	S-01890	Normal	2/6/99	TJoyce	2	N	N	**OK**

T st ID	4	Floor Between hood #1 and hood #2. Sample approx 2 feet in front.							
Test ID User Ref	**04**		Test Type	**Rodac TSA Plate**			Site Type	**Floor**	
Room ID	**5 Micro Lab2 A174**								

Survey#	Test Date	Shift	Test By	SampleID	Room Activity	Read Date	Read By	Reading	TNTC	NoTest	Rslt Status
1010	6/16/99	1	JRadigan	S-00210	Normal	2/6/99	TJoyce	1	N	N	**OK**
1029	7/12/99	3	JRadigan	S-01967	Normal	2/6/99	TJoyce	0	N	N	**OK**

Test ID	5	Floor in center of room.							
Test ID User Ref	**03**		Test Type	**Rodac TSA Plate**			Site Type	**Floor**	
Room ID	**5 Micro Lab2 A174**								

Survey#	Test Date	Shift	Test By	SampleID	Room Activity	Read Date	Read By	Reading	TNTC	NoTest	Rslt Status
1002	7/12/99	1	JRadigan	S-00340	Normal	1/18/99	TJoyce	5	N	N	**OK**
1038	6/16/99	1	JRadigan	S-00940	Normal	2/6/99	TJoyce	7	N	N	**OK**

T st ID	6	Floor in doorway / room entrance							
Test ID User Ref	**01**		Test Type	**Rodac TSA Plate**			Site Type	**Floor**	
Room ID	**5 Micro Lab2 A174**								

Survey#	Test Date	Shift	Test By	SampleID	Room Activity	Read Date	Read By	Reading	TNTC	NoTest	Rslt Status
1002	1/25/99	1	JRadigan	S-00339	Normal	1/25/99	TJoyce	13	N	N	**OK**
1003	7/12/99	1	JRadigan	S-00489	Normal	7/12/99	TJoyce	13	N	N	**OK**
1005	3/22/99	1	JRadigan	S-00789	Normal	3/22/99	TJoyce	3	N	N	**OK**
1038	6/16/99	1	JRadigan	S-00939	Normal	6/16/99	TJoyce	6	N	N	**OK**

Results By Test ID

Facility: **EMS Test Facility**

Test ID 8 Site on work surface of laminar hood 1.

Test ID User Ref **05** Test Type **Rodac TSA Plate** Site Type **Critical Surface**
Room ID **5 Micro Lab2 A174**

Survey#	Test Date	Shift	Test By	SampleID	Room Activity	Read Date	Read By	Reading	TNTC	NoTest	Rslt Status
1001	6/16/99	1	JRadigan	S-00015	Normal	1/11/99	TJoyce	6	N	Y	OK
1038	7/12/99	1	JRadigan	S-00941	Normal	1/25/99	TJoyce	5	N	N	OK

T st ID 10 Personnel touch plate.

Test ID User Ref **T1** Test Type **Touch Plate** Site Type **Glove**
Room ID **5 Micro Lab2 A174**

Survey#	Test Date	Shift	Test By	SampleID	Room Activity	Read Date	Read By	Reading	TNTC	NoTest	Rslt Status
1001	1/4/99	1	JRadigan	S-00020	Normal	1/11/99	TJoyce	6	N	N	OK
1010	2/19/99	1	JRadigan	S-00215	Normal				N	N	
1002	1/11/99	1	JRadigan	S-00345	Normal	1/18/99	TJoyce	16	N	N	> Action
1003	1/18/99	1	JRadigan	S-00495	Normal	1/25/99	TJoyce	1	N	Y	OK
1004	1/25/99	1	JRadigan	S-00645	Normal	2/1/99	TJoyce	7	N	N	OK
1005	2/1/99	1	JRadigan	S-00795	Normal	2/8/99	TJoyce	2	N	N	OK
1038	4/6/99	1	JRadigan	S-00945	Normal				N	N	
1029	2/19/99	3	JRadigan	S-01962	Normal				N	N	
1030	2/19/99	3	JRadigan	S-01977	Normal				N	N	

T st ID 11 Airborne contamination STA plate in center of room.

T st ID User Ref **S1** Test Type **STA Plate** Site Type **Counter**
Room ID **5 Micro Lab2 A174**

Survey#	Test Date	Shift	Test By	SampleID	Room Activity	Read Date	Read By	Reading	TNTC	NoTest	Rslt Status
1001	1/4/99	1	JRadigan	S-00021	Normal	1/9/99	TJoyce	28	N	N	> Action
1010	2/19/99	1	JRadigan	S-00216	Normal				N	N	
1002	1/11/99	1	JRadigan	S-00346	Normal	1/16/99	TJoyce	25	N	N	> Action
1003	1/18/99	1	JRadigan	S-00496	Normal	1/23/99	TJoyce	29	N	N	> Action
1004	1/25/99	1	JRadigan	S-00646	Normal	1/30/99	TJoyce	12	N	N	OK
1005	2/1/99	1	JRadigan	S-00796	Normal	2/6/99	TJoyce	10	N	N	OK
1038	4/6/99	1	JRadigan	S-00946	Normal				N	N	
1030	2/19/99	3	JRadigan	S-01892	Normal				N	N	
1029	2/19/99	3	JRadigan	S-01969	Normal				N	N	
2007	8/5/99	1	JRadigan	+S04130	Normal				N	N	

T st ID	12	Particulate count taken between laminar flow hoods.							
Test ID User Ref	**P1**		Test Type **Non Viable Particulate**			Site Type **Counter**			
Room ID	5	**Micro Lab2 A174**							

Survey #	Test Date	Shift	Test By	SampleID	Room Activity	Read Date	Read By	Reading	TNTC	NoTest	Rslt Status
1001	1/4/99	1	JRadigan	S-00022	Normal	1/4/99	TJoyce	1	N	N	OK
1010	2/19/99	1	JRadigan	S-00217	Normal				N	N	
1002	1/11/99	1	JRadigan	S-00347	Normal	1/11/99	TJoyce	0	N	N	OK
1003	1/18/99	1	JRadigan	S-00497	Normal	1/18/99	TJoyce	5	N	N	> Action
1004	1/25/99	1	JRadigan	S-00647	Normal	1/25/99	TJoyce	5	N	N	> Action
1005	2/1/99	1	JRadigan	S-00797	Normal	2/1/99	TJoyce	6	N	N	> Action
1038	4/6/99	1	JRadigan	S-00947	Normal				N	N	
1030	2/19/99	3	JRadigan	S-01893	Normal				N	N	
1029	2/19/99	3	JRadigan	S-01970	Normal				N	N	
2007	8/5/99	1	JRadigan	+S04131	Normal		JRadigan	9	N	N	> Action

Test ID	13	Floor site in doorway - room entrance.							
Test ID User Ref	**F1**		Test Type **Rodac TSA Plate**			Site Type **Floor**			
Room ID	4	**Micro Lab 1**							

Survey #	Test Date	Shift	Test By	SampleID	Room Activity	Read Date	Read By	Reading	TNTC	NoTest	Rslt Status
1001	1/4/99	1	JRadigan	S-00001	Normal	1/11/99	TJoyce	23	N	N	OK
1002	1/11/99	1	JRadigan	S-00151	Normal	1/18/99	TJoyce	5	N	N	OK
1010	2/19/99	1	JRadigan	S-00197	Normal				N	N	
1003	1/18/99	1	JRadigan	S-00476	Normal	1/25/99	TJoyce	21	N	N	OK
1004	1/25/99	1	JRadigan	S-00626	Normal	2/1/99	TJoyce	2	N	N	OK
1005	2/1/99	1	JRadigan	S-00776	Normal	2/8/99	TJoyce	9	N	N	OK
1011	2/19/99	1	JRadigan	S-01786	Normal				N	N	
1029	2/19/99	3	Callahan	S-01889	Normal				N	N	
1038	4/6/99	1	JRadigan	S-01927	Normal				N	N	
1030	2/19/99	3	JRadigan	S-01973	Normal				N	N	
1061	5/18/99	1	rlindsay	+S03042	Normal	5/25/99	JRadigan	35	N	N	> Action

Environmental Monitoring System

Survey Test Log

Report Date: 10/20/1999

Facility: EMS Test Facility

Test Date	Survey #	Group ID	Group Description	Shift	Product	Lot Number	Incomplete Test Site	Open Readings	Total Tests	Init By	Status
6/25/1998	526	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
7/2/1998	527	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
7/9/1998	528	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
7/16/1998	529	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
7/23/1998	530	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
7/30/1998	531	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
8/6/1998	532	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
8/13/1998	533	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
8/20/1998	534	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
8/27/1998	535	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
9/3/1998	536	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
9/10/1998	537	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
9/17/1998	538	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
9/24/1998	539	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
10/1/1998	540	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
10/8/1998	541	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
10/15/1998	542	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
10/22/1998	543	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
10/29/1998	544	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
11/5/1998	545	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
11/12/1998	546	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
11/19/1998	547	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
11/26/1998	548	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
12/3/1998	549	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
12/10/1998	550	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
1/1/1998	501	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
1/8/1998	502	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
1/15/1998	503	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
1/22/1998	504	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
1/29/1998	505	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
2/5/1998	506	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
2/12/1998	507	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
2/19/1998	508	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
2/26/1998	509	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
3/5/1998	510	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
3/12/1998	511	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
3/19/1998	512	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
3/26/1998	513	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed

CSSC Pharmaceuticals

Survey Test Log

Environmental Monitoring
Syst m

Report Date: 10/20/1999

Facility: EMS Test Facility

Test Date	Survey #	Group ID	Group Description	Shift	Product	Lot Number	Incomplete Test Site	Open Readings	Total Tests	Init By	Status
4/2/1998	514	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
4/9/1998	515	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
4/16/1998	516	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
4/23/1998	517	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
4/30/1998	518	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
5/7/1998	519	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
5/14/1998	520	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
5/21/1998	521	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
5/28/1998	522	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
6/4/1998	523	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
6/11/1998	524	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
6/18/1998	525	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
12/17/1998	551	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
12/24/1998	552	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
1/4/1999	1001	2	Weekly Tests	1	None	None	0	0	150	VGalliani	Closed
1/11/1999	1002	2	Weekly Tests	1	None	None	0	0	150	VGalliani	Closed
1/18/1999	1003	2	Weekly Tests	1	None	None	0	0	150	VGalliani	Closed
1/25/1999	1004	2	Weekly Tests	1	None	None	0	0	150	VGalliani	Closed
2/1/1999	1005	2	Weekly Tests	1	None	None	0	0	150	VGalliani	Closed
2/17/1999	1007	4	Production Room Daily	1	None	None	0	0	13	JRadigan	Open
	1008	4	Production Room Daily	1	None	None	0	0	13	JRadigan	Open
	1009	4	Production Room Daily	1	None	None	0	0	13	JRadigan	Open
2/19/1999	1010	2	Weekly Tests	1	None	None	149	149	149	JRadigan	In Proc
	1012	4	Production Room Daily	1	None	None	0	0	13	JRadigan	Open
	1013	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open
	1014	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open
	1015	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open
	1016	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open
	1017	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open
	1018	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open
	1019	3	Daily Tests	1	None	None	6	7	7	JRadigan	In Proc
	1020	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open
	1021	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open
	1022	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open
	1023	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open
	1024	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open
	1025	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open
	1026	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open

CSSC Pharmaceuticals

Report Date: 10/20/1999

Facility: EMS Test Facility

Test Date	Survey #	Group ID	Group Description	Shift	Product	Lot Number	Incomplete Test Site	Open Readings	Total Tests	Init By	Status
2/19/1999	1027	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open
	1028	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open
	1029	0	Released By Test or Room	1	None	None	0	0	15	JRadigan	Open
	1030	0	Released By Test or Room	1	None	None	17	17	17	JRadigan	In Proc
	1031	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open
	1032	0	Released By Test or Room	1	None	None	0	0	4	JRadigan	Open
	1033	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open
	1034	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open
2/23/1999	1035	3	Insert Group Name Here	1	None	None	0	0	7	JRadigan	Open
	1036	4	Insert Group Name Here	1	None	None	0	0	13	JRadigan	Open
2/26/1999	1037	3	Insert Group Name Here	1	None	None	0	0	7	JRadigan	Open
4/6/1999	1038	2	Insert Group Name Here	1	None	None	0	0	149	JRadigan	Open
4/22/1999	1039	3	Insert Group Name Here	1	None	None	0	6	7	JRadigan	Closed
	1040	3	Insert Group Name Here	1	None	None	0	4	7	JRadigan	Closed
	1041	3	Insert Group Name Here	1	None	None	0	6	7	JRadigan	Closed
	1042	3	Insert Group Name Here	1	None	None	6	7	7	JRadigan	In Proc
	1043	3	Insert Group Name Here	1	None	None	3	5	7	JRadigan	In Proc
	1044	3	Insert Group Name Here	1	None	None	7	7	7	JRadigan	In Proc
4/30/1999	1045	3	Daily Tests	1	None	None	7	7	7	JRadigan	Open
5/7/1999	1046	3	Daily Tests	1	None	None	2	6	7	JRadigan	In Proc
	1047	3	Daily Tests	1	None	None	7	7	7	JRadigan	In Proc
	1048	3	Daily Tests	1	None	None	7	7	7	JRadigan	In Proc
	1049	3	Daily Tests	1	None	None	0	5	7	JRadigan	Closed
5/10/1999	1050	3	Daily Tests	1	None	None	7	7	7	JRadigan	In Proc
	1051	3	Daily Tests	1	None	None	7	7	7	JRadigan	Open
	1052	3	Daily Tests	1	None	None	7	7	7	JRadigan	Open
	1053	3	Daily Tests	1	None	None	7	7	7	JRadigan	In Proc
	1054	3	Daily Tests	1	None	None	7	7	7	JRadigan	Open
	1055	3	Daily Tests	1	None	None	7	7	7	JRadigan	Open
7/13/1999	1504	4	Production Room Daily Tests	1	rrrr	rrrr	13	13	13	jradigan	Open
	1505	3	Daily Tests	1	None	None	13	13	13	jradigan	Open
	1507	3	Daily Tests	1	tttt	tttt	13	13	13	jradigan	Open
	1509	3	Daily Tests	1	gbnmm	nmbnmbnm	13	13	13	jradigan	Open
7/22/1999	2000	3	Daily Tests	1	uuuy	tituituitu	13	13	13	jradigan	Open
7/29/1999	2001	3	Daily Tests	1	666666	666666	12	12	13	jradigan	In Proc
8/5/1999	2004	3	Daily Tests	1	cvcvcv	cvcvcv	12	14	13	jradigan	In Proc
	2005	3	Daily Tests	1	uiouio	ouioiuo	13	15	13	jradigan	In Proc

CSSC Pharmaceuticals
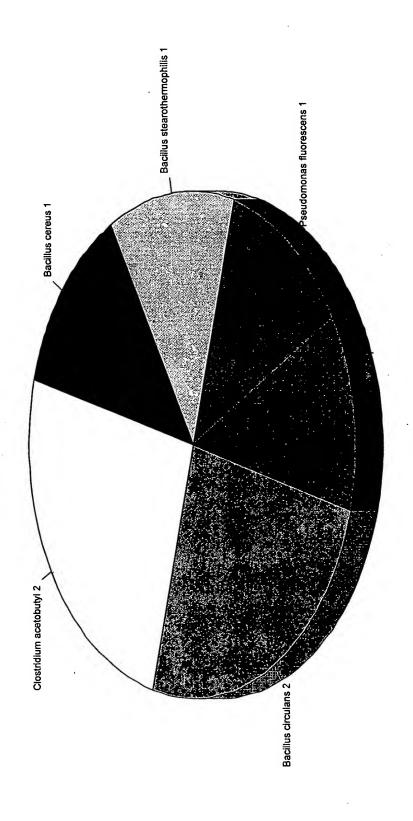
Environmental Monitoring
Sy tem

Report Date: 10/20/1999
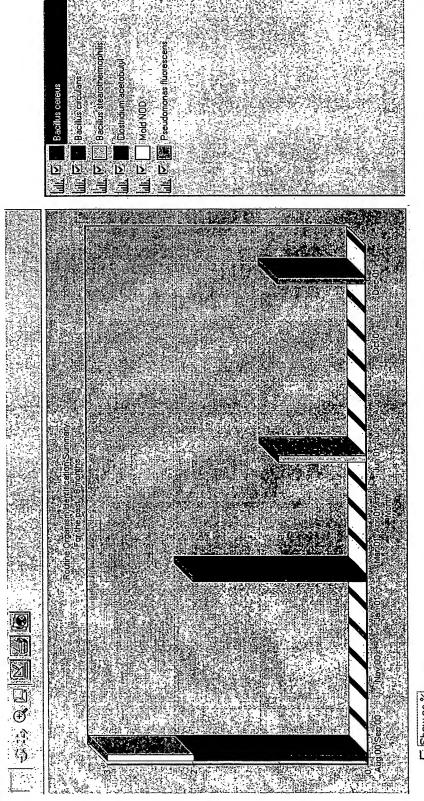
Survey Test Log

Facility: **EMS Test Facility**

Test Date	Survey #	Group ID	Group Description	Shift	Product	Lot Number	Incomplete Test Site	Open Readings	Total Tests	Init By	Status
8/5/1999	2006	3	Daily Tests	1	efsef	sfsdfsd	6	8	13	jradigan	In Proc
	2007	0	Manually Created Survey	1	thrthh	rthrthr	3	3	3	jradigan	In Proc
8/10/1999	2008	3	Daily Tests	1	None	None	13	13	13	jradigan	Open
	2009	3	Daily Tests	1	None	None	13	13	13	jradigan	Open
8/25/1999	2010	3	Daily Tests	1	None	None	14	14	13	jradigan	In Proc
	2011	3	Daily Tests	2	None	None	15	15	15	jradigan	In Proc
9/2/1999	2012	3	Daily Tests	1	hjfjhgjhfh	jutuytuy	6	9	14	jradigan	In Proc
9/7/1999	2013	3	Daily Tests	1	jtujtujty	tiutuitui	7	13	14	jradigan	In Proc
10/14/1999	2014	3	Daily Tests	1	P-WFI10ml	1234-66JK7	14	14	14	jradigan	In Proc
10/19/1999	2015	3	Daily Tests	1	1313131	11111-44	13	13	14	jradigan	In Proc

Organism Summary

Bacillus stearothermophilis 1

Pseudomonas fluorescens 1

Bacillus cereus 1

Clostridium acetobutyl 2

Bacillus circulans 2

Environmental Monitoring System

Organism Identification Listing

Report Date: 1/16/2002

SampleDate	Organism Type	Genus/Species Name	TestID	Sample ID	Test ID Description	Objectionable
00-January						
1/20/00	Bacteria	Bacillus circulans	1443	+S04606A	Water Conductivity	N
00-August						
8/5/00	Bacteria	Bacillus circulans	35	+S05316A	RCS airborne contamination sample taken in center of clean area.	N
8/5/00	Bacteria	Clostridium acetobutyl	35	+S05316A	RCS airborne contamination sample taken in center of clean area.	N
8/5/00	Mold	Mold NOD	35	+S05316A	RCS airborne contamination sample taken in center of clean area.	N
01-February						
2/20/01	Bacteria	Clostridium acetobutyl	17	+S07802A	Floor site in center of room.	N
2/20/01	Other	Bacillus cereus	18	+S07803A	Site on work surface of laminar flow hood.	N
01-June						
6/5/01	Bacteria	Bacillus stearothermophilis	18	+S08529A	Site on work surface of laminar flow hood.	N
01-December						
12/5/01	Bacteria	Pseudomonas fluorescens	16	SB000002A	Floor site in front of sinks.	N

CSSC Pharmaceuticals

Environmental Monitoring System

R port Period - From: 01/01/2001   To: 01/16/2002

Report Date: 1/16/2002   Facility: EMS Test Facility

Sample ID: +S08483A   **Selected Reading:**   None

Sample ID: +S08524A   **Selected Reading:**   Reading 2

R ading 1: 10   **Reading 1 Date:** 11/1/2001 9:00:00AM   **Reading 1 By:** TJoyce

R ading 2: 5   **Reading 2 Date:** 11/1/2001 9:00:00AM   **Reading 2 By:** TJoyce

Average of the Two Readings: 8

Sample ID: +S08525A   **Selected Reading:**   Average

R ading 1: 14   **Reading 1 Date:** 12/1/2001 6:00:00AM   **Reading 1 By:** VGalliani

R ading 2: 15   **Reading 2 Date:** 12/1/2001 6:00:00AM   **Reading 2 By:** VGalliani

Average of the Two Readings: 14

Sample ID: +S08526A   **Selected Reading:**   Average

R ading 1: 12   **Reading 1 Date:** 12/2/2001 7:00:00AM   **Reading 1 By:** VGalliani

R ading 2: 17   **Reading 2 Date:** 12/2/2001 7:00:00AM   **Reading 2 By:** VGalliani

Average of the Two Readings: 14

Sample ID: +S08527A   **Selected Reading:**   None

Sample ID: SB000002A   **Selected Reading:**   None

Sample ID: SB000004A   **Selected Reading:**   Reading 2

R ading 1: 10   **Reading 1 Date:** 12/5/2001 1:00:00PM   **Reading 1 By:** TJoyce

Reading 2: 5   **Reading 2 Date:** 12/5/2001 1:00:00PM   **Reading 2 By:** TJoyce

Average of the Two Readings: 8

Environmental Monitoring System

Multiple Samples

Report Date: 1/16/2002   Facility: EMS Test Facility

Report Period - From: 01/01/2001   To: 01/16/2002

Sample ID: +S08533A

Number of Package Units: 3.0(Number of Samples / Unit: 4.0(

	Package Unit 1	Package Unit 2	Package Unit 3
Sample 1	12	12	6
Sample 2	2	4	8
Sample 3	12	5	9
Sample 4	6	3	12

Average / Mean:	8

Environmental Monitoring System

Report Date: 1/16/2002

Sample ID	Review By	Review Date
Surv y Number: 1001		
+S05313A	JRadigan	4/21/1999 6:29:59AM
+S05314A	JRadigan	4/25/1999 8:29:59PM
+S05315A	JRadigan	4/23/1999 5:29:59PM
+S05316A	JRadigan	4/22/1999 1:29:59AM
+S05317A	JRadigan	4/20/1999 6:29:59AM
+S05318A	JRadigan	4/15/1999 8:29:59AM
+S05319A	JRadigan	4/28/1999 7:29:59AM
+S05320A	JRadigan	4/27/1999 8:29:59AM
+S05321A	JRadigan	4/25/1999 10:29:59AM
+S05322A	JRadigan	4/27/1999 8:29:59AM
+S05323A	JRadigan	4/24/1999 12:29:59AM
+S05323B	JRadigan	4/26/1999 2:29:59PM
+S05324A	JRadigan	4/24/1999 6:29:59PM
+S05325A	JRadigan	4/15/1999 2:29:59AM
+S05326A	JRadigan	4/20/1999 10:29:59AM
+S05327A	JRadigan	4/19/1999 10:29:59AM
+S05328A	JRadigan	4/18/1999 3:29:59AM
+S05329A	JRadigan	4/19/1999 6:29:59PM
+S05330A	JRadigan	4/18/1999 10:29:59PM
+S05331A	JRadigan	4/19/1999 7:29:59AM
+S05332A	JRadigan	4/23/1999 1:29:59PM
+S05333A	JRadigan	4/24/1999 7:29:59AM
+S05334A	JRadigan	4/24/1999 4:29:59PM
+S05335A	JRadigan	4/23/1999 7:29:59AM
+S05336A	JRadigan	4/24/1999 1:29:59PM
+S05337A	glevinson	1/9/2002 1:59:12PM
+S05338A	JRadigan	4/27/1999 6:29:59PM
+S05339A	JRadigan	4/28/1999 1:29:59AM
+S05340A	JRadigan	4/25/1999 9:29:59PM
+S05341A	JRadigan	4/20/1999 4:29:59PM
+S05342A	JRadigan	4/23/1999 5:29:59PM
+S05343A	JRadigan	4/15/1999 2:29:59AM
+S05344A	JRadigan	4/27/1999 10:29:59PM
+S05345A	JRadigan	4/27/1999 7:29:59AM
+S05346A	JRadigan	4/24/1999 2:29:59AM
+S05347A	JRadigan	4/24/1999 4:29:59AM
+S05348A	JRadigan	4/26/1999 11:29:59AM
+S05349A	JRadigan	4/24/1999 9:29:59PM
+S05350A	JRadigan	4/22/1999 9:29:59PM
+S05351A	JRadigan	4/26/1999 3:29:59PM
+S05351B	JRadigan	4/27/1999 12:29:59PM
+S05352A	JRadigan	4/24/1999 6:29:59PM
+S05353A	JRadigan	4/19/1999 1:29:59AM

Environmental Monitoring System

Report Date: 1/16/2002

Sample ID	Review By	Review Date
Survey Number: 1002		
+S05354A	JRadigan	4/30/1999 6:29:59PM
+S05355A	JRadigan	4/29/1999 1:29:59AM
+S05356A	JRadigan	5/2/1999 1:29:59PM
+S05357A	JRadigan	4/28/1999 8:29:59PM
+S05358A	JRadigan	4/24/1999 4:29:59PM
+S05359A	JRadigan	4/21/1999 9:29:59PM
+S05360A	JRadigan	4/30/1999 5:29:59AM
+S05361A	JRadigan	4/28/1999 3:29:59AM
+S05362A	JRadigan	4/29/1999 10:29:59AM
+S05363A	JRadigan	5/3/1999 1:29:59AM
+S05364A	JRadigan	4/28/1999 4:29:59AM
+S05364B	JRadigan	4/29/1999 5:29:59PM
+S05365A	JRadigan	5/1/1999 3:29:59AM
+S05366A	JRadigan	4/23/1999 4:29:59AM
+S05367A	JRadigan	4/27/1999 1:29:59AM
+S05368A	JRadigan	4/24/1999 9:29:59PM
+S05369A	JRadigan	4/24/1999 9:29:59PM
+S05370A	JRadigan	4/22/1999 4:29:59PM
+S05371A	JRadigan	4/25/1999 7:29:59PM
+S05372A	JRadigan	4/27/1999 3:29:59AM
+S05373A	JRadigan	5/2/1999 4:29:59PM
+S05374A	JRadigan	4/29/1999 2:29:59PM
+S05375A	JRadigan	4/28/1999 12:29:59PM
+S05376A	JRadigan	5/3/1999 12:29:59PM
+S05377A	JRadigan	4/28/1999 12:29:59PM
+S05378A	JRadigan	5/1/1999 7:29:59PM
+S05379A	JRadigan	5/1/1999 10:29:59PM
+S05380A	JRadigan	5/3/1999 5:29:59AM
+S05381A	JRadigan	5/2/1999 5:29:59AM
+S05382A	JRadigan	4/26/1999 9:29:59PM
+S05383A	JRadigan	4/28/1999 10:29:59AM
+S05384A	JRadigan	4/26/1999 5:29:59AM
+S05385A	JRadigan	5/2/1999 8:29:59PM
+S05386A	JRadigan	4/28/1999 10:29:59AM
+S05387A	JRadigan	4/30/1999 6:29:59AM
+S05388A	JRadigan	4/29/1999 6:29:59AM
+S05389A	JRadigan	5/2/1999 7:29:59PM
+S05390A	JRadigan	5/4/1999 8:29:59PM
+S05391A	JRadigan	5/1/1999 10:29:59AM
+S05392A	JRadigan	5/4/1999 2:29:59AM
+S05392B	JRadigan	4/28/1999 3:29:59PM
+S05393A	JRadigan	4/27/1999 2:29:59PM
+S05394A	JRadigan	4/27/1999 10:29:59PM

Summary of Reviewed Surveys

Report Date: 1/16/2002

Sample ID	Review By	Review Date
Survey Number: 1003		
+S05395A	JRadigan	5/12/1999 5:30:00AM
+S05396A	JRadigan	5/6/1999 5:30:00PM
+S05397A	JRadigan	5/8/1999 5:30:00PM
+S05398A	JRadigan	5/7/1999 7:30:00PM
+S05399A	JRadigan	5/4/1999 2:30:00AM
+S05400A	JRadigan	4/29/1999 9:30:00AM
+S05401A	JRadigan	5/5/1999 9:30:00AM
+S05402A	JRadigan	5/10/1999 9:30:00PM
+S05403A	JRadigan	5/7/1999 10:30:00PM
+S05404A	JRadigan	5/5/1999 7:30:00AM
+S05405A	JRadigan	5/10/1999 10:30:00AM
+S05405B	JRadigan	5/6/1999 12:30:00AM
+S05406A	JRadigan	5/6/1999 4:30:00PM
+S05407A	JRadigan	4/30/1999 4:30:00PM
+S05408A	JRadigan	5/4/1999 8:30:00AM
+S05409A	JRadigan	4/29/1999 1:30:00AM
+S05410A	JRadigan	5/3/1999 12:30:00AM
+S05411A	JRadigan	4/27/1999 11:30:00PM
+S05412A	JRadigan	4/30/1999 4:30:00AM
+S05413A	JRadigan	5/3/1999 2:30:00AM
+S05414A	JRadigan	5/5/1999 11:30:00PM
+S05415A	JRadigan	5/12/1999 4:30:00AM
+S05416A	JRadigan	5/5/1999 9:30:00AM
+S05417A	JRadigan	5/5/1999 5:30:00AM
+S05418A	JRadigan	5/11/1999 6:30:00PM
+S05419A	JRadigan	5/6/1999 9:30:00AM
+S05420A	JRadigan	5/5/1999 2:30:00PM
+S05421A	JRadigan	5/4/1999 10:30:00PM
+S05422A	JRadigan	5/6/1999 11:30:00PM
+S05423A	JRadigan	5/4/1999 9:30:00AM
+S05424A	JRadigan	5/10/1999 1:30:00AM
+S05425A	JRadigan	4/30/1999 12:30:00AM
+S05426A	JRadigan	5/8/1999 2:30:00PM
+S05427A	JRadigan	5/12/1999 2:30:00AM
+S05428A	JRadigan	5/9/1999 3:30:00AM
+S05429A	JRadigan	5/11/1999 12:30:00AM
+S05430A	JRadigan	5/10/1999 4:30:00PM
+S05431A	JRadigan	5/10/1999 2:30:00PM
+S05432A	JRadigan	5/8/1999 2:30:00PM
+S05433A	JRadigan	5/11/1999 7:30:00PM
+S05433B	JRadigan	5/5/1999 1:30:00PM
+S05434A	JRadigan	5/9/1999 3:30:00PM
+S05435A	JRadigan	5/1/1999 10:30:00AM

Sample Operational Documents

Environm ntal Monitoring System

Report Date: 4/3/2000

Survey Contol No. **2076**	Facility: **EMS Test Facility**
Survey Date: 4/3/2000	Group **Daily Tests**
Survey Shift: 1	

Room ID: **6**

RefNo **MicroSterility**

Room Description
Micr Sterility Suite
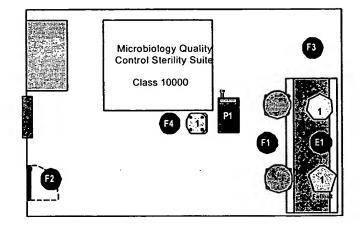
Microbiology Quality
Control Sterility Suite

Class 10000

Activity Level	☐ Static
	☐ Operational

Non Viable Particulate	Sample Date / Time	On Test Date / Time	Equipment ID/ Reading
Test ID: Test Ref Site Type Test Description	Sample By	On Test By	
45 P1 Counter	———— ————	———— ————	Equip ————
Particulate count taken in room center.	———— ————	———— ————	Read ☐
	+S05265A		

Rodac TSA Plate	Sample Date / Time	On Test Date / Time	Equipment ID/ Media Lot
Test ID: Test Ref Site Type Test Description	Sample By	On Test By	
38 F1 Floor	———— ————	———— ————	Equip ————
Floor site in front of laminar flow hood.	———— ————	———— ————	Media ————
	+S05259A		
39 F2 Floor	———— ————	———— ————	Equip ————
Flo r site in doorway - room entrance.	———— ————	———— ————	Media ————
	+S05260A		
40 F3 Floor	———— ————	———— ————	Equip ————
Floor site in room corner - general cleanliness assessment.	———— ————	———— ————	Media ————
	+S05261A		
41 E1 Critical Surface	———— ————	———— ————	Equip ————
Sit on work surface of laminar flow hood.	———— ————	———— ————	Media ————
	+S05262A		

Print # 0001

Review By: _____ Date: _____

CSSC Pharmaceuticals

Environmental Monitoring Syst m

Report Date: 4/3/2000

Survey Contol No.	**2076**	Facility:	**EMS Test Facility**
Survey Date:	4/3/2000	Group	**Daily Tests**
Survey Shift:	1		

STA Plate

Test ID:	Test Ref	Site Type / Test Description	Sample Date / Time / Sample By	On Test Date / Time / On Test By	Equipment ID/ Media Lot
44	1	Counter	———	———	Equip ———
		STA airborne contamination sample taken in room center.	——— +S05264A	———	Media ———

Touch Plate

Test ID:	Test Ref	Site Type / Test Description	Sample Date / Time / Sample By	On Test Date / Time / On Test By	Emp ID/ Media Lot
42	TP1	Glove	———	———	Emp ID [ ]
		Touch plate taken within laminar flow hood.	——— +S05263A	———	Media ———
42	TP1	Glove	———	———	Emp ID [ ]
		Touch plate taken within laminar flow hood.	——— +S05263B	———	Media ———

Water pH

Test ID:	Test Ref	Site Type / Test Description	Sample Date / Time / Sample By	On Test Date / Time / On Test By	Equipment ID/ Reading
1432	WFI-000-1	Water	———	———	Equip ———
		Point Of Use site at WFI Drop	——— +S05266A	———	Read [ ]

Review By: _____   Date: _____

CSSC Pharmaceuticals

Environmental Monitoring System

Report Date: 4/3/2000

Survey Contol No. **2076**	Facility: **EMS Test Facility**
Survey Date: 4/3/2000	Group **Daily Tests**
Survey Shift: 1	

Room ID: 7

RefNo **MicroGowning**

Room Description
Micro Gowning Area

Microbiology Quality Control Gowning Area

Class 1000 / 10000

Activity Level

☐ Static

☐ Operational
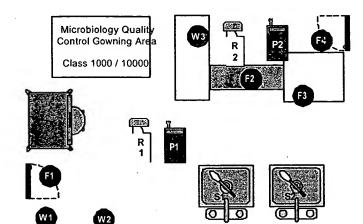
Non Viable Particulate			Sample Date / Time	On Test Date / Time	Equipment ID/ Reading
Test ID:	Test Ref	Site Type / Test Description	Sample By	On Test By	
36	P1	Counter	———————	———————	Equip ———————
		Particulate count taken in center of wash area.	——————— +S05257A	———————	Read [ ]
37	P2	Counter	———————	———————	Equip ———————
		Particulate count taken in center of clean area.	——————— +S05258A	———————	Read [ ]

RCS Air Sample			Sample Date / Time	On Test Date / Time	Equipment ID/ Media Lot
Test ID:	Test Ref	Site Type / Test Description	Sample By	On Test By	
34	R1	Counter	———————	———————	Equip ———————
		RCS airborne contamination sample taken in center of wash area.	——————— +S05255A	———————	Media ———————
35	R2	Counter	———————	———————	Equip ———————
		RCS airborne contamination sample taken in center of cl an area.	——————— +S05256A	———————	Media ———————

Review By: _____ Date: _____

CSSC Pharmaceuticals

Environmental Monitoring System

Report Date: 4/3/2000

Survey Contol No.	**2076**	Facility: **EMS Test Facility**
Survey Date:	4/3/2000	Group **Daily Tests**
Survey Shift:	1	

Surface Swab	Sample Date / Time Sample By	On Test Date / Time On Test By	Equipment ID/ Media Lot
Test ID: **Test Ref** Site Type Test Description			
32 S1 Work Surface	_____	_____	Equip _____
Swab sample within sink 1.	_____	_____	Media _____
	+S05253A		
33 S2 Work Surface	_____	_____	Equip _____
Swab sample within sink 2.	_____	_____	Media _____
	+S05254A		

Review By: _____ Date: _____

CSSC Pharmaceuticals

Environmental Monitoring System

Report Date: 4/3/2000

Survey Contol No.	**2076**
Survey Date:	4/3/2000
Survey Shift:	1

Facility: **EMS Test Facility**

Group **Daily Tests**

Room ID: **74**

RefNo **Water System**
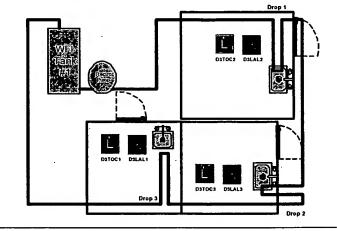
Room Description

Wat r System

Activity Level	☐ Static
	☐ Operational

Water Conductivity			Sample Date / Time	On Test Date / Time	Equipment ID/ Reading
Test ID:	Test Ref	Site Type Test Description	Sample By	On Test By	
1443	WFI=003-02	Water	_____	_____	Equip _____
	Water Conductivity		_____	_____	Read [ ]
			+S05271A		

Water Endotoxin EU/ml			Sample Date / Time	On Test Date / Time	Equipment ID/ Reading
Test ID:	Test Ref	Site Type Test Description	Sample By	On Test By	
1433	D1LAL1	Water	_____	_____	Equip _____
	Water Endotoxin at Drop 1 in Production Room A		_____	_____	Read [ ]
			+S05267A		
1435	D3LAL3	Water	_____	_____	Equip _____
	Water Endotoxin test at Drop 3 in Production Prep Room		_____	_____	Read [ ]
			+S05268A		

Review By: _____ Date: _____

CSSC Pharmaceuticals

Environmental Monitoring System

Report Date: 4/3/2000

Survey Contol No.	**2076**	Facility:	**EMS Test Facility**
Survey Date:	4/3/2000	Group	**Daily Tests**
Survey Shift:	1		

Water pH	Sample Date / Time	On Test Date / Time	Equipment ID / Reading
Test ID: Test Ref Site Type Test Description	Sample By	On Test By	
1436 D1PH1 Water **Water pH at Drop 1 in Production Room A**	_____ _____ **+S05269A**	_____ _____	Equip _____ Read [ ]
1438 D3PH3 Water **Water pH at Drop 3 in Production Prep Room**	_____ _____ **+S05270A**	_____ _____	Equip _____ Read [ ]

Review By: _____   Date: _____

CSSC Pharmaceuticals

Survey #	Room	Test Type	Test ID
2076	7	Surface Swab	32

S1

`* ¡ SO5253A *`

+S05253A Date: / Time: 4/3/00

By _____

Survey #	Room	Test Type	Test ID
2076	7	Surface Swab	33

S2

`* ¡ SO5254A *`

+S05254A Date: / Time: 4/3/00

Survey #	Room	Test Type	Test ID
2076	7	RCS Air Sample	34

R1

`* ¡ SO5255A *`

+S05255A Date: / Time: 4/3/00

By _____

Survey #	Room	Test Type	Test ID
2076	7	RCS Air Sample	35

R2

`* ¡ SO5256A *`

+S05256A Date: / Time: 4/3/00

By _____

Survey #	Room	Test Type	Test ID
2076	7	Non Viable Particulate	36

P1

`* ¡ SO5257A *`

+S05257A Date: / Time: 4/3/00

By _____

Survey #	Room	Test Type	Test ID
2076	7	Non Viable Particulate	37

P2

`* ¡ SO5258A *`

+S05258A Date: / Time: 4/3/00

By _____

Survey #	Room	Test Type	Test ID
2076	6	Rodac TSA Plate	38

F1

`* ¡ SO5259A *`

+S05259A Date: / Time: 4/3/00

By _____

Survey #	Room	Test Type	Test ID
2076	6	Rodac TSA Plate	39

F2

`* ¡ SO5260A *`

+S05260A Date: / Time: 4/3/00

By _____

Survey #	Room	Test Type	Test ID
2076	6	Rodac TSA Plate	40

F3

`* ¡ SO5261A *`

+S05261A Date: / Time: 4/3/00

By _____

Survey #	Room	Test Type	Test ID
2076	6	Rodac TSA Plate	41

E1

`* ¡ SO5262A *`

+S05262A Date: / Time: 4/3/00

By _____

Survey #	Room	Test Type	Test ID
2076	6	Touch Plate	42

TP1

`* ¡ SO5263A *`

+S05263A Date: / Time: 4/3/00

By _____

Survey #	Room	Test Type	Test ID
2076	6	Touch Plate	42

TP1

`* ¡ SO5263B *`

+S05263B Date: / Time: 4/3/00

By _____

Survey #	Room	Test Type	Test ID
2076	6	STA Plate	44

1

`* ¡ SO5264A *`

+S05264A Date: / Time: 4/3/00

By _____

Survey #	Room	Test Type	Test ID
2076	6	Non Viable Particulate	45

P1

`* ¡ SO5265A *`

+S05265A Date: / Time: 4/3/00

By _____

Survey #	Room	Test Type	Test ID
2076	6	Water pH	1432

WFI-000-1

`* ¡ SO5266A *`

+S05266A Date: / Time: 4/3/00

By _____

Survey #	Room	Test Type	Test ID
2076	74	Water Endotoxin EU/ml	1433

D1LAL1

`* ¡ SO5267A *`

+S05267A Date: / Time: 4/3/00

By _____

Survey #	Room	Test Type	Test ID
2076	74	Water Endotoxin EU/ml	1435

D3LAL3

`* ¡ SO5268A *`

+S05268A Date: / Time: 4/3/00

By _____

Survey #	Room	Test Type	Test ID
2076	74	Water pH	1436

D1PH1

`* ¡ SO5269A *`

+S05269A Date: / Time: 4/3/00

By _____

Survey #	Room	Test Type	Test ID
2076	74	Water pH	1438

D3PH3

`* ¡ SO5270A *`

+S05270A Date: / Time: 4/3/00

By _____

Survey #	Room	Test Type	Test ID
2076	74	Water Conductivity	1443

WFI=003-02

`* ¡ SO5271A *`

+S05271A Date: / Time: 4/3/00

By _____

Environm ntal Monitoring System

Report Date: __4/3/2000__

RCS Air Sampl

Control	Test ID Scheduled Read Date: Ref #	Test Description Room Description Test Type	Sample ID Alert Limit Action Limit	Read Date Time: Read By:	Result: Ref Doc:
2073	Group	**Daily Tests**			
2073	**34**	RCS airborne contamination sample taken in center of wash area.	**+S05198A**		
	3/21/00 8:54AM		40		
	R1	Micro Gowning Area	50		
		RCS Air Sample			
2073	**35**	RCS airborne contamination sample taken in center of clean area.	**+S05199A**		
	3/21/00 10:30AM		30		
	R2	Micro Gowning Area	40		
		RCS Air Sample			

Environmental Monitoring System

Report Date: **4/3/2000**

RCS Air Sample

Control	Test ID Scheduled Read Date: Ref #		Test Description Room Description Test Type	Sample ID Alert Limit Action Limit	Read Date Time: Read By:	Result: Ref Doc:
2075		Group	**Daily Tests**			
2075	34		RCS airborne contamination sample taken in center of wash area.	+S05236A		
	4/3/00 9:30AM			40		
		R1	Micro Gowning Area	50		
			RCS Air Sample			
2075	35		RCS airborne contamination sample taken in center of clean area.	+S05237A		
	4/3/00 9:45AM			30		
		R2	Micro Gowning Area	40		
			RCS Air Sample			

Environmental Monitoring System

Report Date: **4/3/2000**

Rodac TSA Plate

Control	Test ID Scheduled Read Date: Ref #		Test Description Room Description Test Type	Sample ID Alert Limit Action Limit	Read Date Time: Read By:	Result: Ref Doc:
2073		Group	**Daily Tests**			
2073	**41**		Site on work surface of laminar flow hood.	**+S05205A**		
	3/23/00	7:00AM		15		
		E1	Micro Sterility Suite	18		
			Rodac TSA Plate			

Environmental Monitoring System

Survey Confirmation Worksheet

Report Date: 4/3/2000

Facility: **Current Facility**
Group: **Daily Tests**

Survey Contol No.: 2069
Survey Date: 3/6/00
Survey Shift: 1

Product: **sqd**
Lot #: **xdwx**

Room ID: 6   RefNo   **MicroSterility**

Room Description
Micro Sterility Suite

Rodac TSA Plate

Test ID Ref	Test ID	Test Site Description	Sample Date / Sample By	Test Date / Test By	Media Lot / Equipment ID	Sample ID / Room Activity	Exception	Entry By / Enter Date
E1	41	Site on work surface of laminar flow hood.	3/6/00 7:23AM TNucci	3/6/00 7:23AM TNucci	1234R01 None	+S05146A Operational		iradigan 3/22/00 10:27PM
F1	38	Floor site in front of laminar flow hood.	3/6/00 7:05AM TNucci	3/6/00 7:05AM TNucci	1234R014 None	+S05143A Operational		iradigan 3/22/00 10:27PM
F2	39	Floor site in doorway - room entrance.	3/6/00 7:15AM TNucci	3/6/00 7:15AM TNucci	1234R01 None	+S05144A Operational		iradigan 3/22/00 10:27PM
F3	40	Floor site in room corner - general cleanliness assessment.	3/6/00 7:22AM TNucci	3/6/00 7:22AM TNucci	1234R01 None	+S05145A Operational		iradigan 3/22/00 10:27PM

Non Viable Particulate

Test ID Ref	Test ID	Test Site Description	Sample Date / Sample By	Test Date / Test By	Media Lot / Equipment ID	Sample ID / Room Activity	Result Exception	Entry By / Enter Date
P1	45	Particulate count taken in room center.	3/6/00 7:15AM JRadigan	3/6/00 7:15AM JRadigan	None 123444	+S05149A Operational	1	iradigan 3/22/00 11:15PM

Print #: 0002
Reviewed By: _____   Date: _____

CSSC Pharmaceuticals

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Environmental Monitoring System

Survey Confirmation Worksheet

Report Date: 4/3/2000

Facility: **Current Facility**
Group: **Daily Tests**

Survey Contol No.: 2069

Survey Date:	3/6/00	Product:	sqd
Survey Shift:	1	Lot #:	xdwx

Room ID: 6   RefNo   **MicroSterility**

Room Description
Micro Sterility Suite

Touch Plate

Test ID Ref	Test ID	Test Site Description	Sample Date / Sample By	Test Date / Test By	Media Lot / Equipment ID	Sample ID / Room Activity	Exception / Employee II	Entry By / Enter Date
GeorgeL	42	Touch plate taken within laminar flow hood.	3/6/00 9:25AM TNucci	3/6/00 9:25AM TNucci	1234R01	+S05147A Operational	GeorgeL	jradigan 3/22/00 11:18PM
RLindsay	42	Touch plate taken within laminar flow hood.	3/6/00 9:26AM TNucci	3/6/00 9:26AM TNucci	1234R01	+S05147B Operational	RLindsay	jradigan 3/22/00 11:18PM

STA Plate

Test ID Ref	Test ID	Test Site Description	Sample Date / Sample By	Test Date / Test By	Media Lot / Equipment ID	Sample ID / Room Activity	Exception	Entry By / Enter Date
1	44	STA airborne contamination sample taken in room center.	3/6/00 10:25AM TestQATech	3/6/00 10:25AM TestQATech	1234R01 None	+S05148A Operational		jradigan 3/22/00 11:18PM

Water pH

Test ID Ref	Test ID	Test Site Description	Sample Date / Sample By	Test Date / Test By	Media Lot / Equipment ID	Sample ID / Room Activity	Result / Exception	Entry By / Enter Date
WFI-000-1	1432	Point Of Use site at WFI Drop	3/6/00 1:30PM TNucci	3/6/00 1:30PM TNucci	None None	+S05150A Operational	6.3	jradigan 3/22/00 11:18PM

Print #: 0002

Reviewed By: _____   Date: _____

CSSC Pharmaceuticals

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Environmental Monitoring System

Survey Confirmation Worksheet

Report Date: 4/3/2000

Survey Contol No.	2069
Survey Date:	3/6/00
Survey Shift:	1

Facility:	**Current Facility**
Group:	**Daily Tests**

Product:	**sqd**
Lot #:	**xdwx**

Room ID: 7   RefNo   **MicroGowning**

Room Description
Micro Gowning Area

RCS Air Sample

Test ID Ref	Test ID	Test Site Description	Sample Date / Sample By	Test Date / Test By	Media Lot / Equipment ID	Sample ID / Room Activity	Exception	Entry By / Enter Date
R1	34	RCS airborne contamination sample taken in center of wash area.	3/6/00 10:00AM TNucci	3/6/00 10:00AM TNucci	None None	+S05139A Operational		iradiqan 3/22/00 11:18PM
R2	35	RCS airborne contamination sample taken in center of clean area.	3/6/00 11:00AM TNucci	3/6/00 11:00AM TNucci	1234 Q232	+S05140A Operational		iradiqan 3/22/00 11:18PM

Non Viable Particulate

Test ID Ref	Test ID	Test Site Description	Sample Date / Sample By	Test Date / Test By	Media Lot / Equipment ID	Sample ID / Room Activity	Result / Exception	Entry By / Enter Date
P1	36	Particulate count taken in center of wash area.	3/6/00 8:00AM TNucci	3/6/00 8:00AM TNucci	None	+S05141A Operational	4 Alert	iradiqan 3/22/00 10:01PM
P2	37	Particulate count taken in center of clean area.	3/6/00 8:05AM TNucci	3/6/00 8:05AM TNucci	None	+S05142A Operational	1	iradiqan 3/22/00 10:01PM

Print #: 0002

Reviewed By: _____   Date: _____

CSSC Pharmaceuticals

Environmental Monitoring System

Survey Confirmation Worksheet

Report Date: 4/3/2000

Survey Contol No.   2069

Facility:	**Current Facility**
Group:	**Daily Tests**

Survey Date: 3/6/00
Survey Shift: 1

Product: **sqd**
Lot #: **xdwx**

Room ID: 7   RefNo   **MicroGowning**

Room Description
Micro Gowning Area

Surface Swab

Test ID:Ref	Test ID	Test Site Description	Sample Date / Sample By	Test Date / Test By	Media Lot / Equipment ID	Sample ID / Room Activity	Exception	Entry By / Enter Date
S1	32	Swab sample within sink 1.	3/6/00 8:55AM TNucci	3/6/00 8:55AM TNucci	11111111	**+S05137A** Operational		iradiqan 3/22/00 11:18PM
		- tt4hrthrth - 22222222222 - Reason #3						
S2	33	Swab sample within sink 2.	3/6/00 8:56AM TNucci	3/6/00 8:56AM TNucci	11111111	**+S05138A** Operational		iradiqan 3/22/00 11:18PM

Print #: 0002

Reviewed By: _____   Date: _____

CSSC Pharmaceuticals

Environmental Monitoring System

Report Date: 4/3/2000

Facility: **Current Facility**
Group: **Daily Tests**

Survey Contol No. **2069**

Survey Date: 3/6/00   Product: **sqd**
Survey Shift: 1   Lot #: **xdwx**

Room ID: 74   RefNo   **Water System**   Room Description
Water System

Water Endotoxin EU/ml

Test ID Ref	Test ID	Test Site Description	Sample Date / Sample By	Test Date / Test By	Media Lot / Equipment ID	Sample ID / Room Activit)	Result / Exception	Entry By / Enter Date
D1LAL1	1433	Water Endotoxin at Drop 1 in Production Room A	3/6/00 8:23AM TNucci	3/6/00 11:05AM GeorgeL	1234	+S05151A Operational	5.200	jradigan 3/22/00 11:18PM
D3LAL3	1435	Water Endotoxin test at Drop 3 in Production Prep Room	3/6/00 8:24AM TNucci	3/6/00 9:25AM GeorgeL	1234	+S05152A Operational	0.530	jradigan 3/22/00 11:18PM

Water pH

Test ID Ref	Test ID	Test Site Description	Sample Date / Sample By	Test Date / Test By	Media Lot / Equipment ID	Sample ID / Room Activit)	Result / Exception	Entry By / Enter Date
D1PH1	1436	Water pH at Drop 1 in Production Room A	3/6/00 10:05AM TNucci	3/6/00 10:05AM TNucci	12345R M-002	+S05153A Operational	<0.8	jradigan 3/22/00 11:18PM
		Yes						
D3PH3	1438	Water pH at Drop 3 in Production Prep Room	3/6/00 10:07AM TNucci	3/6/00 10:07AM TNucci	12345R M-002	+S05154A Operational	4.6	jradigan 3/22/00 11:18PM

Water Conductivity

Test ID Ref	Test ID	Test Site Description	Sample Date / Sample By	Test Date / Test By	Media Lot / Equipment ID	Sample ID / Room Activit)	Result / Exception	Entry By / Enter Date
WFI=003-02	1443	Water Conductivity	3/6/00 10:45AM TNucci	3/6/00 10:45AM TNucci	M-002	+S05155A Operational	>4.5	jradigan 3/22/00 11:18PM
		NQ Reason						

Print #: 0002

Reviewed By: _____ Date: _____

CSSC Pharmaceuticals

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Environmental Monitoring System

Survey Results

Report Date: 4/3/2000

Facility: **EMS Test Facility**
Group: **Daily Tests**

Survey Contol No. ...2069

Product: **sqd**
Lot #: **xdwx**

Survey Date: 3/6/00
Survey Shift: 1

Room ID: 6   RefNo   **MicroSterility**

Room Description
Micro Sterility Suite

Rodac TSA Plate

Test ID Ref	Test ID	Test Site Description	Sample Date / Sample By / Media Lot	Test Date / Test By / Equipment ID	Result Date / Result By	Sample ID / Room Activity	Result Exception	Entry By / Enter Date
E1	41	Site on work surface of laminar flow hood.	3/6/00 7:23AM TNucci 1234R01	3/6/00 7:23AM TNucci None	3/13/00 9:10AM VGalliani	+S05146A Operational	1	iradiqan 3/22/00 10:27PM
F1	38	Floor site in front of laminar flow hood.	3/6/00 7:05AM TNucci 1234R014	3/6/00 7:05AM TNucci None	3/13/00 8:00AM JRadiqan	+S05143A Operational	18	iradiqan 3/22/00 10:27PM
F2	39	Floor site in doorway - room entrance.	3/6/00 7:15AM TNucci 1234R01	3/6/00 7:15AM TNucci None	3/13/00 9:00AM TJoyce	+S05144A Operational	22	iradiqan 3/22/00 10:27PM
F3	40	Floor site in room corner - general cleanliness assessment.	3/6/00 7:22AM TNucci 1234R01	3/6/00 7:22AM TNucci None	3/13/00 9:05AM TJoyce	+S05145A Operational	8	iradiqan 3/22/00 10:27PM

Print #: 0

Reviewed By: _____   Date: _____

CSSC Pharmaceuticals

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Environmental Monitoring System

Report Date: 4/3/2000

Survey Contol No.	2069
Survey Date:	3/6/00
Survey Shift:	1

Facility: **EMS Test Facility**
Group: **Daily Tests**

Product: **sqd**
Lot #: **xdwx**

Room ID: 6   RefNo   **MicroSterility**

Room Description
Micro Sterility Suite

Non Viable Particulate

Test ID Ref	Test ID	Test Site Description	Sample Date / Sample By / Media Lot	Test Date / Test By / Equipment ID	Result Date / Result By	Sample ID / Room Activity	Result / Exception	Entry By / Enter Date
P1	45	Particulate count taken in room center.	3/6/00 7:15AM JRadigan None	3/6/00 7:15AM JRadigan 123444	3/6/00 7:15AM JRadigan	+S05149A Operational	1	jradigan 3/22/00 11:15PM

Touch Plate

Test ID Ref	Test ID	Test Site Description	Sample Date / Sample By / Media Lot	Test Date / Test By / Equipment ID	Result Date / Result By	Sample ID / Room Activity	Result / Exception / Employee ID	Entry By / Enter Date
GeorgeL	42	Touch plate taken within laminar flow hood.	3/6/00 9:25AM TNucci 1234R01	3/6/00 9:25AM TNucci	3/13/00 10:00AM JRadigan	+S05147A Operational	2 GeorgeL	jradigan 3/22/00 11:18PM
RLindsay	42	Touch plate taken within laminar flow hood.	3/6/00 9:26AM TNucci 1234R01	3/6/00 9:26AM TNucci	3/13/00 10:00AM RLindsay	+S05147B Operational	2 RLindsay	jradigan 3/22/00 11:18PM

STA Plate

Test ID Ref	Test ID	Test Site Description	Sample Date / Sample By / Media Lot	Test Date / Test By / Equipment ID	Result Date / Result By	Sample ID / Room Activity	Result / Exception	Entry By / Enter Date
1	44	STA airborne contamination sample taken in room center.	3/6/00 10:25AM TestQATech 1234R01	3/6/00 10:25AM TestQATech None	3/11/00 11:00AM VGalliani	+S05148A Operational	3	jradigan 3/22/00 11:18PM

Print #:   0

Reviewed By: _____   Date: _____

CSSC Pharmaceuticals

Environmental Monitoring System

Survey Results

Report Date: 4/3/2000

Facility: **EMS Test Facility**
Group: **Daily Tests**

Survey Contol No. 2069

Product: **sqd**
Lot #: **xdwx**

Survey Date: 3/6/00
Survey Shift: 1

Room Description
Micro Sterility Suite

Room ID: 6   RefNo   **MicroSterility**

Water pH

Test ID Ref	Test ID	Test Site Description	Sample Date / Sample By / Media Lot	Test Date / Test By / Equipment ID	Result Date / Result By	Sample ID / Room Activity	Result / Exception	Entry By / Enter Date
WFI-000-1	1432	Point Of Use site at WFI Drop	3/6/00 1:30PM / TNucci / None	3/6/00 1:30PM / TNucci / None	3/6/00 2:50PM / TJoyce	+S05150A / Operational	6.3	iradiqan / 3/22/00 11:18PM

Print #:   0

Reviewed By: _____

Date: _____

CSSC Pharmaceuticals

Environmental Monitoring System

Report Date: 4/3/2000

Facility: **EMS Test Facility**
Group: **Daily Tests**

Survey Contol No.: 2069

Product: **sqd**
Lot #: **xdwx**

Survey Date: 3/6/00
Survey Shift: 1

Room ID: 7   RefNo **MicroGowning**

Room Description
Micro Gowning Area

RCS Air Sample

Test ID Ref	Test ID	Test Site Description	Sample Date / Sample By / Media Lot	Test Date / Test By / Equipment ID	Result Date / Result By	Sample ID / Room Activity	Result / Exception	Entry By / Enter Date
R1	34	RCS airborne contamination sample taken in center of wash area.	3/6/00 10:00AM TNucci None	3/6/00 10:00AM TNucci None	3/11/00 10:00AM JRadigan	+S05139A Operational	2	iradigan 3/22/00 11:18PM
R2	35	RCS airborne contamination sample taken in center of clean area.	3/6/00 11:00AM TNucci 1234	3/6/00 11:00AM TNucci Q232	3/11/00 1:50PM JRadigan	+S05140A Operational	2	iradigan 3/22/00 11:18PM

Non Viable Particulate

Test ID Ref	Test ID	Test Site Description	Sample Date / Sample By / Media Lot	Test Date / Test By / Equipment ID	Result Date / Result By	Sample ID / Room Activity	Result / Exception	Entry By / Enter Date
P1	36	Particulate count taken in center of wash area.	3/6/00 8:00AM TNucci	3/6/00 8:00AM TNucci None	3/6/00 8:00AM TNucci	+S05141A Operational	4 **Alert**	iradigan 3/22/00 10:01PM
P2	37	Particulate count taken in center of clean area.	3/6/00 8:05AM TNucci	3/6/00 8:05AM TNucci None	3/6/00 8:05AM TNucci	+S05142A Operational	1	iradigan 3/22/00 10:01PM

Print #: 0

Reviewed By: _____   Date: _____

CSSC Pharmaceuticals

Environmental Monitoring System

Survey Results

Report Date: 4/3/2000

| | | | | Facility: | EMS Test Facility |
| | | | | Group: | Daily Tests |

Survey Contol No. **2069**

		Product:	sqd
Survey Date:	3/6/00	Lot #:	xdwx
Survey Shift:	1		

Room Description
Micro Gowning Area

| Room ID: | 7 | RefNo | MicroGowning |

Surface Swab

Test ID Ref	Test ID	Test Site Description	Sample Date / Sample By / Media Lot	Test Date / Test By / Equipment ID	Result Date / Result By	Sample ID / Room Activity	Result / Exception	Entry By / Enter Date
S1	32	Swab sample within sink 1.	3/6/00 8:55AM TNucci 11111111	3/6/00 8:55AM TNucci	3/13/00 1:15PM RWatson	+S05137A Operational	9	iradiqan 3/22/00 11:18PM
		- tt4hrthrth - 22222222222 - Reason #3						
S2	33	Swab sample within sink 2.	3/6/00 8:56AM TNucci 11111111	3/6/00 8:56AM TNucci	3/13/00 2:30PM RLindsay	+S05138A Operational	2	iradiqan 3/22/00 11:18PM

Print #: 0

Reviewed By: _____ Date: _____

CSSC Pharmaceuticals

Environmental Monitoring System

Report Date: 4/3/2000

Facility: **EMS Test Facility**
Group: **Daily Tests**

Survey Contol No. 2069

Product: **sqd**
Lot #: **xdwx**

Survey Date: 3/6/00
Survey Shift: 1

Room ID: 74 RefNo **Water System**

Room Description
Water System

Water Endotoxin EU/ml

Test ID Ref	Test ID	Test Site Description	Sample Date / Sample By / Media Lot	Test Date / Test By / Equipment ID	Result Date / Result By	Sample ID / Room Activit)	Result Exception	Entry By / Enter Date
D1LAL1	1433	Water Endotoxin at Drop 1 in Production Room A	3/6/00 8:23AM TNucci	3/6/00 11:05AM GeorgeL 1234	3/6/00 1:35PM TJoyce	+S05151A Operational	5.200	iradigan 3/22/00 11:18PM
D3LAL3	1435	Water Endotoxin test at Drop 3 in Production Prep Room	3/6/00 8:24AM TNucci	3/6/00 9:25AM GeorgeL 1234	3/6/00 1:35PM TJoyce	+S05152A Operational	0.530	iradigan 3/22/00 11:18PM

Water pH

Test ID Ref	Test ID	Test Site Description	Sample Date / Sample By / Media Lot	Test Date / Test By / Equipment ID	Result Date / Result By	Sample ID / Room Activit)	Result Exception	Entry By / Enter Date
D1PH1	1436	Water pH at Drop 1 in Production Room A	3/6/00 10:05AM TNucci 12345R	3/6/00 10:05AM TNucci M-002	3/6/00 4:30PM TJoyce	+S05153A Operational	<0.8	iradigan 3/22/00 11:18PM
		Yes						
D3PH3	1438	Water pH at Drop 3 in Production Prep Room	3/6/00 10:07AM TNucci 12345R	3/6/00 10:07AM TNucci M-002	3/6/00 4:25PM TJoyce	+S05154A Operational	4.6	jradigan 3/22/00 11:18PM

Print#: 0

Reviewed By: _____ Date: _____

CSSC Pharmaceuticals

Environmental Monitoring System

Survey Results

Report Date: 4/3/2000

Facility: **EMS Test Facility**
Group: **Daily Tests**

Survey Contol No.   2069

Product:	**sqd**
Lot #:	**xdwx**

Survey Date: 3/6/00
Survey Shift: 1

Room ID: 74   RefNo **Water System**

Room Description
Water System

Water Conductivity

Test ID Ref	Test ID	Test Site Description	Sample Date / Sample By / Media Lot	Test Date / Test By / Equipment ID	Result Date / Result By	Sample ID / Room Activity	Result / Exception	Entry By / Enter Date
WFI=003-02	1443	Water Conductivity	3/6/00 10:45AM TNucci	3/6/00 10:45AM TNucci M-002	3/6/00 10:45AM TNucci	+S05155A Operational	>4.5	iradiqan 3/22/00 11:18PM
		NQ Reason						

Print #: 0

Reviewed By: _____   Date: _____

CSSC Pharmaceuticals

Microbial Over Action Limits Investigation   **Control No. 2047**

Sample Date **09/02/1999**   Product name   **P-WFI20ml-002**   Lot   **12345-SD-55** Room: **6 Production Fill Line #6** Sample Site   **38 - Floor site in front of laminar flow hood.** Result **35**   Alert Level   **20**   Action Level   **25**

Trending information.   Dates trended: From   **10/12/1998** To **10/12/1999**

List dates of any excursions for
this site and the results

Date	Result

Dates subsequent samples and the results   ___/___/___ _____   ___/___/___ _____
                                                                   ___/___/___ _____

Product Sterility Test Result: Pass   Fail Endotoxin results: Pass   Fail (if a gram negative isolate only):
Microbial Characterization potential source of organism 1. VITEK Id Number: _____.   VITEK characterization: _____ _____ 2. API 20 E Lot No. _____ Exp. Date: _____ API 20E Id No. _____ API 20 E Characterization_____ 3. API 20NE Lot No. _____ Exp. Date: _____ API 20NE Id No. _____ API 20NE Characterization_____ Suspected Source of organism: _____
List any calibration or maintenance that has been done in the area that may have affected the site _____ _____

Comments _____
_____
_____

Investigation Conducted by _____   Date _____

Reviewed by _____   Date _____

Microbial Monitoring Advers Trend Report

To: _____

_____

_____

From: Microbiology Supervisor

The following site has developed an adverse trend and needs immediate attention.

Sample Date **09/07/1999**	
Room: **6**	
Sample Site	**41 - Site on work surface of laminar flow hood.**
Result **16** Alert Level **15** Action Level **18**	

Trending information.   Dates trended: From   **10/14/1998** To **10/14/1999**

This section to be filled out by the manager or supervisor responsible for the area

Possible cause for the trend _____
_____
_____
_____

Corrective action and date implemented
_____
_____
_____
_____

Signature _____   Title _____   Date _____

This Section to be filled out by Microbiology Supervisor or designee

Results of samplings since the corrective action _____
_____
_____

Is the corrective action effective based upon the results?   ____ Yes ____ No

Signature _____   Title _____   Date _____

Objectionable Microbial Organism Notification Report

To: _____

_____

From: **Environm ntal Monitoring System**

During routine organism identification monitoring, the following objectionable organism was detected. ***Bacillus cereus***

Sample Date **03/23/2000**
Survey Number: **1050**   Sample ID: **+S07354A**
Room: **5 - Micro Lab2 A174**
Sample Site **4 - Floor Between hood #1 and hood #2. Sample approx 2 feet in front.**
Result **44**   Alert Level **10**   Action Level **15**

Trending information.   Dates trended: From **07/28/1999** To **07/28/2000**

This section to be filled out by the manager or supervisor responsible for the area

Possible cause for the appearance of this organism _____

_____

_____

_____

Corrective action and date implemented

_____

_____

_____

_____

Signature _____   Title _____   Date _____

This Section to be filled out by Microbiology Supervisor or designee

Results of samplings since the corrective action _____

_____

_____

Is the corrective action effective based upon the results? ____ Yes ____ No

Signature _____   Title _____   Date _____

Environmental Monitoring System

Out of Limits Deviation Report

Control Number	2015	Close Status	Yes
Surv y Number	1046		
Sample ID	0/09992		

Report Date 10/20/99

Test Date	**5/7/99 7:57:00AM** Shift **2** Group	**Weekly Assesment**	
Test ID	**40**	Room Desc	**Micro Sterility Suite**
Test User Ref	**R-002-B**		
Test Desc	**Floor site in room corner - general cleanliness assessment.**		
Test Type	**Rodac Plates TSA**		
Read Date	**5/14/99 5:25:00AM**	Read By	**JRadigan**
Reading	**33.00**	AlertLimit **0.00** **25.00**	Action Limit **0.00** **30.00**
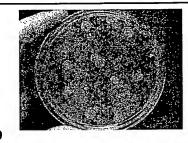
Investigation Activities

Check Maint Log	Yes
Check Cleaning Log	Yes
Review Batch Record Data	Yes
Verify Training Records	Yes
Review Other OOL Cond	Yes
Check Utilities	Yes
Verify Calibration Docs	Yes
Review Lab Docs	Yes
Review Test Procedures	Yes
Other	No

Investigation Narative

Review of all logs revealed no adverse events. Training documents were reviewed and all were found to be current. All production and lab documents were reviewed and no descrepancies were found.

Organism Identifications

Obs	Source	Report ID	Equipment ID	ID Date	ID By
1	Vitek	10424	1224-NF	5/18/99 12:00:00AM	JRadigan
	Gram Stain	Microscopic	Organism Type	Species	
	Neg	**rod**	**Bacteria**	**Bacillus subtillus**	
Obs	Source	Report ID	Equipment ID	ID Date	ID By
2	Vitek	12377	1224-NF	5/18/99 12:00:00AM	JRadigan
	Gram Stain	Microscopic	Organism Type	Species	
	Pos	**rod**	**Bacteria**	**Bacillus stearothermophilis**	

Corrective Action

Gowniing and production procedures were reviewed with all production technicians. Cleaning procedures were also reviewed with cleaning crew.

Conclusions

No single cause ciuld be determined as review of documents and procedures did not identify any deviations from normal routine. It is concluded that there the cause is most probably due to technician contamination. All technicians involved in production on this date were counselled and aseptic gowning and operational procedures were reviewed. Subsequent testing demonstrated return to normal levels.

Close Date 9/13/99 8:41:48AM   Close By   jradigan

CSSC Pharmac uticals

Sample Database Listing

Environmental Monitoring System

Report Date: 10/20/99

Facility Listing

Facility ID	Facility Name	Active Status	Last Maint Date	Last Maint By	Req Equip	Req Media Lot	Assign Samp ID	Review Date	Review Freq
2	EMS Test Facility	Yes	10/2/99	jradigan	Yes	Yes	Yes	5/1/99	Monthly
3	Test QA/QC Facility	No	8/25/99	jradigan	No	No	No	6/1/99	Monthly
4	Jordan Validation	Yes	8/25/99	jradigan	Yes	Yes	Yes	6/1/99	Annually
5	Jordan Pharmaceuticals	Yes	8/23/99	jradigan	Yes	Yes	Yes	6/1/99	Annually
8	Test Jordan Facility	Yes	9/8/99	jradigan	No	No	Yes	6/1/99	Quarterly
9	New Water Facility	Yes	9/28/99	jradigan	Yes	Yes	Yes		Annually
10	EMS Test Facility 2	Yes	10/14/99	jradigan	Yes	Yes	Yes		Annually

Environmental Monitoring System

Report Date: 10/20/99

Facility ID Facility Name

2   EMS Test Facility

Active Status: Yes

	Last Maint Date	Last Review Date
	10/2/99	5/1/99
	Last Maint By	Review Frequency
	jradigan	Monthly

Auto Sample ID No.   Yes
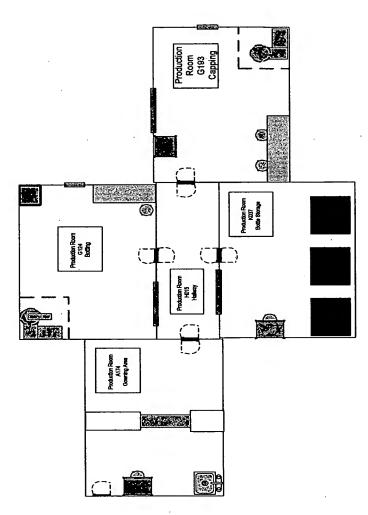
Require Media Lot   Yes

Require Equipment ID   Yes

Production Room
G183
Capping

Production Room
G124
Bottling

Production Room
K007
Bottle Storage

Production Room
H015
Hallway

Production Room
A174
Gowning Area

CSSC Pharmaceuticals

Facility Layout

Environmental Monitoring System

Report Date   10/20/99

Facility ID   2   Name   EMS Test Facility

Room ID   4   Room Ref No   A174

Room Description

Micro Lab 1

Room X   0   Room Y   0

Room Classification   Class 10,000

Production Area Classification   Not Classified
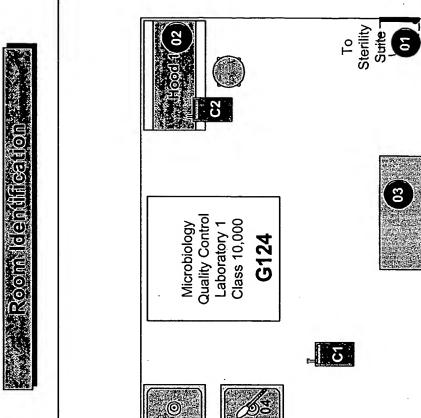
Last Maint Date   1999/10/18 09:38:12.00

LastMaint By   jradigan

Room Identification

Microbiology
Quality Control
Laboratory 1
Class 10,000

G124

To
Sterility
Suite

CSSC Pharmaceuticals

Environmental Monitoring System

Report Date   10/20/99

Room ID   5   Room Ref No   MicroLab2 A1

Room Description

Micro Lab2 A174

Room X   0   Room Y   0

Room Classification   Class 10,000

Production Area Classification   Class 100
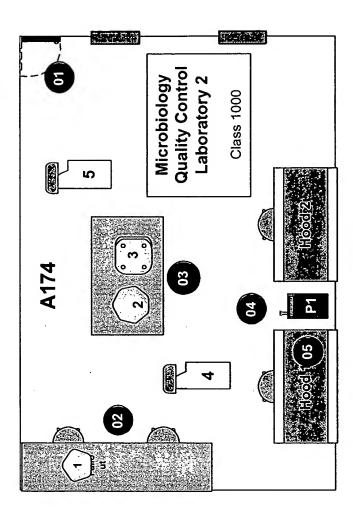
Last Maint Date   1999/09/30 04:28:35.00

LastMaint By   jradigan

A174

Microbiology
Quality Control
Laboratory 2

Class 1000

01

02

03

04

05

P1

Hood1

Hood2

1

2

3

4

5

CSSC Pharmaceuticals

Page   2

Environmental Monitoring System

Room Identification

Report Date   10/20/99

Room ID   **6**   Room-Ref No   **MicroSterility**

Room Description

Micro Sterility Suite

Room X   **0**   Room Y   **0**

Room Classification   **Class 100,000**

Production Area Classification   **Class 100**
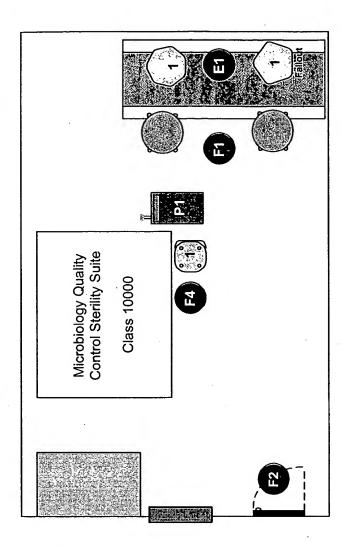
Last Maint Date   **1999/08/26 15:45:46.00**

LastMaint By   **jradigan**

Microbiology Quality
Control Sterility Suite

Class 10000

CSSC Pharmaceuticals

Environmental Monitoring System

Report Date:

Site ID	Site Description
1	Wall
2	Floor
3	Glove
4	Garment
5	Production Surface
6	Work Surface
7	Critical Surface
8	Counter
9	Door
10	Water
11	Pressure
12	Sink
13	Room Air
14	HEPA Curtains
15	Tools
16	Ceiling
17	General assessment site.
18	Pass-through
19	Non-Viable Particulate
20	Equipment

Environmental Monitoring System

Report Date: 10/20/99

Facility **EMS Test Facility**

Room ID	Room Ref
4	**A174**

Room Description
Micro Lab 1
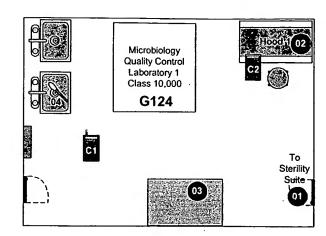
Classification
Not Classified

Microbiology
Quality Control
Laboratory 1
Class 10,000
G124

Hood 1 02
C2
04
C1
To
Sterility
Suite
03
01

Rodac TSA Plate
RODAC.ICO

Test ID	Test Description		Test SOP	One Side Lot Specific	Min Alert Limit Min Action Limit	Max Alert Limit Max Action Limit
Test Ref	**Test Cat**	**Site Desc**				
13	Floor site in doorway - room entrance.			True	0.000	25.000
F1	Viable	Floor		False	0.000	30.000
Test Memo						
14	Floor site in front of laminar flow hood.			False	0.000	25.000
F2	Viable	Floor		False	0.000	30.000
Test Memo						
15	Floor site in doorway - to sterility suite.			True	0.000	25.000
F3	Viable	Floor		False	0.000	30.000
Test Memo						
16	Floor site in front of sinks.			True	0.000	30.000
F4	Viable	Floor		False	0.000	35.000
Test Memo						
17	Floor site in center of room.			True	0.000	25.000
F5	Viable	Floor		False	0.000	30.000
Test Memo						
18	Site on work surface of laminar flow hood.			True	0.000	15.000
E1	Viable	Critical Surface		False	0.000	20.000
Test Memo						

RCS Air Sample
RCS.ico

Test ID	Test Description		Test SOP	One Side Lot Specific	Min Alert Limit Min Action Limit	Max Alert Limit Max Action Limit
Test Ref	**Test Cat**	**Site Desc**				
22	Touch plate taken on work surface.			True	0.000	22.000
ZZ1	Viable	Glove		False	0.000	30.000
Test Memo						

Non Viable Particulate
Particle.ico

Test ID	Test Description		Test SOP	One Side Lot Specific	Min Alert Limit Min Action Limit	Max Alert Limit Max Action Limit
Test Ref	**Test Cat**	**Site Desc**				
24	Particulate count taken in room center.			True	0.000	3.000
P1	NonViable	Counter		False	0.000	7.000
Test Memo						

CSSC Pharmaceuticals

Environmental Monitoring System

Report Date: 10/20/99

Facility   **EMS Test Facility**

Fallout Plate   SAS.ico

Test ID	Test Description		Test SOP	One Side Lot Specific	Min Alert Limit Min Action Limit	Max Alert Limit Max Action Limit
Test Ref	Test Cat	Site Desc				
21		Fallout plate within laminar flow hood.		True	0.000	20.000
1	Viable	Critical Surface		False	0.000	25.000
Test Memo						

STA Plate   STA.ico

Test ID	Test Description		Test SOP	One Side Lot Specific	Min Alert Limit Min Action Limit	Max Alert Limit Max Action Limit
Test Ref	Test Cat	Site Desc				
23		Airborne contamination count taken in center of room.		True	0.000	30.000
1	Viable	Counter		False	0.000	40.000
Test Memo						

Surface Swab   Swab.ico

Test ID	Test Description		Test SOP	One Side Lot Specific	Min Alert Limit Min Action Limit	Max Alert Limit Max Action Limit
Test Ref	Test Cat	Site Desc				
19		Swab sample within sink 1.		True	0.000	40.000
S1	Viable	Work Surface		False	0.000	50.000
Test Memo						
20		Swab sample within sink 2.		True	0.000	40.000
S2	Viable	Work Surface		False	0.000	50.000
Test Memo						

Environmental Monitoring System

Facility   **EMS Test Facility**

Report Date:	10/20/99

Room ID	Room Ref
5	**MicroLab2 A174**
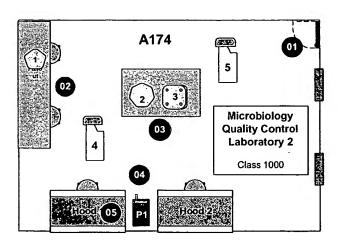
Room Description
Micro Lab2 A174

Classification
Class 10,000

RODAC.ICO

Rodac TSA Plate

Test ID	Test Description			One Side	Min Alert Limit	Max Alert Limit
Test Ref	Test Cat	Site Desc	Test SOP	Lot Specific	Min Action Limit	Max Action Limit
3	Floor between workstations approx 2 feet in front of work table.			True	0.000	4.000
02	Viable	Floor	iiii	False	0.000	6.000
Test Memo						
4	Floor Between hood #1 and hood #2. Sample approx 2 feet in front.			True	0.000	10.000
04	Viable	Floor		False	0.000	15.000
Test Memo						
5	Floor in center of room.			False	0.000	13.000
03	Viable	Floor		False	0.000	15.000
Test Memo						
6	Floor in doorway / room entrance			True	0.000	13.000
01	Viable	Floor		False	0.000	15.000
Test Memo						
7	Floor in room corner - assess general room cleanliness.			True	0.000	20.000
F5	Viable	Floor		False	0.000	30.000
Test Memo						
8	Site on work surface of laminar hood 1.			True	0.000	12.000
05	Viable	Critical Surface		False	0.000	15.000
Test Memo						
9	Site on work surface of laminar hood 2.			False	0.000	12.000
E2	Viable	Critical Surface		False	0.000	15.000
Test Memo						

NonViable Particulate

Particle.ico

Test ID	Test Description			One Side	Min Alert Limit	Max Alert Limit
Test Ref	Test Cat	Site Desc	Test SOP	Lot Specific	Min Action Limit	Max Action Limit
12	Particulate count taken between laminar flow hoods.			True	0.000	3.000
P1	NonViable	Counter		False	0.000	7.000
Test Memo						

Touch Plate

Touch.ico

Test ID	Test Description			One Side	Min Alert Limit	Max Alert Limit
Test Ref	Test Cat	Site Desc	Test SOP	Lot Specific	Min Action Limit	Max Action Limit

CSSC Pharmaceuticals

Environmental Monitoring System

Report Date: 10/20/99

Facility   **EMS Test Facility**

Test ID	Test Description			Test SOP	One Side / Lot Specific	Min Alert Limit / Min Action Limit	Max Alert Limit / Max Action Limit
10	Personnel touch plate.				True	0.000	15.000
T1	Viable	Glove		rrr	True	0.000	20.000
Test Memo	tyrtytryrtyty						

STA Plate   STA.ico

Test ID	Test Description			Test SOP	One Side / Lot Specific	Min Alert Limit / Min Action Limit	Max Alert Limit / Max Action Limit
Test Ref	**Test Cat**	**Site Desc**					
11	Airborne contamination STA plate in center of room.				True	0.000	20.000
S1	Viable	Counter			False	0.000	30.000
Test Memo							

Environmental Monitoring System

Report Date: 10/20/99

Facility **EMS** **Test Facility**

Room ID	Room Ref
6	**MicroSterility**
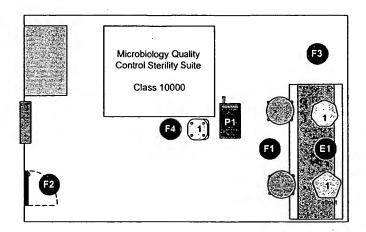
Room Description
Micro Sterility Suite

Classification
Not Classified

Microbiology Quality
Control Sterility Suite

Class 10000

Rodac TSA Plate   RODAC.ICO

Test ID	Test Description		Test SOP	One Side Lot Specific	Min Alert Limit Min Action Limit	Max Alert Limit Max Action Limit
Test Ref	Test Cat	Site Desc				
38	Floor site in front of laminar flow hood.			True	0.000	20.000
F1	Viable	Floor		False	0.000	25.000
Test Memo						
39	Floor site in doorway - room entrance.			True	0.000	25.000
F2	Viable	Floor		False	0.000	30.000
Test Memo						
40	Floor site in room corner - general cleanliness assessment.			True	0.000	25.000
F3	Viable	Floor		False	0.000	30.000
Test Memo						
41	Site on work surface of laminar flow hood.			True	0.000	15.000
E1	Viable	Critical Surface		False	0.000	18.000
Test Memo						

Non Viable Particulate   Particle.ico

Test ID	Test Description		Test SOP	One Side Lot Specific	Min Alert Limit Min Action Limit	Max Alert Limit Max Action Limit
Test Ref	Test Cat	Site Desc				
45	Particulate count taken in room center.			True	0.000	2.000
P1	NonViable	Counter		False	0.000	5.000
Test Memo						

Touch Plate   Touch.ico

Test ID	Test Description		Test SOP	One Side Lot Specific	Min Alert Limit Min Action Limit	Max Alert Limit Max Action Limit
Test Ref	Test Cat	Site Desc				
42	Touch plate taken within laminar flow hood.			True	0.000	15.000
1	Viable	Glove		False	0.000	18.000
Test Memo						

Fallout Plate   SAS.ico

Test ID	Test Description		Test SOP	One Side Lot Specific	Min Alert Limit Min Action Limit	Max Alert Limit Max Action Limit
Test Ref	Test Cat	Site Desc				

Environmental Monitoring System

Facility   **EMS T st Facility**

Report Date: 10/20/99

43	Fallout plate taken within laminar flow hood.			True	0.000	10.000
1	Viable	Critical Surface		False	0.000	15.000
Test Memo						

STA Plate   STA.ico

Test ID	Test Description			One Side	Min Alert Limit	Max Alert Limit
Test Ref	Test Cat	Site Desc	Test SOP	Lot Specific	Min Action Limit	Max Action Limit
44	STA airborne contamination sample taken in room center.			True	0.000	20.000
1	Viable	Counter		False	0.000	25.000
Test Memo						

Water pH   ChemGen.ico

Test ID	Test Description			One Side	Min Alert Limit	Max Alert Limit
Test Ref	Test Cat	Site Desc	Test SOP	Lot Specific	Min Action Limit	Max Action Limit
1432	Point Of Use site at WFI Drop			False	5.500	7.200
WFI-000-1	Water	Water	WFI -122222	False	6.000	7.900
Test Memo						

Environmental Monitoring System

Report Date: 10/20/99

Facility: **EMS Test Facility 2**

Room ID	**99**	Room Description	**Room G124**

Test ID	Test User Ref		Test ID Description

1428   01   Floor Rodac

								Min	

Test Type   **Rodac TSA Plate**
Site Desc   **Floor**
Category   **Viable**

Classification
Class 10,000

	Max		Min
One Side **Yes**	Alert Limit	**15.000**	**0.000**
	Action Limit	**21.000**	**0.000**

Test SOP   JJ123456
Lot Specific   No
Maint Date   10/18/99   Maint By   jradigan
Test Memo

1429   02   Counter Rodac

Test Type   **Rodac TSA Plate**
Site Desc   **Work Surface**
Category   **Viable**

Classification
Class 10,000

	Max		Min
One Side **Yes**	Alert Limit	**22.000**	**0.000**
	Action Limit	**37.000**	**0.000**

Test SOP   JJ666688
Lot Specific   No
Maint Date   9/30/99   Maint By   jradigan
Test Memo

1430   03   Work Surface

Test Type   **Rodac TSA Plate**
Site Desc   **Work Surface**
Category   **Viable**

Classification
Class 10,000

	Max		Min
One Side **Yes**	Alert Limit	**12.000**	**0.000**
	Action Limit	**18.000**	**0.000**

Test SOP   jj890777
Lot Specific   No
Maint Date   9/30/99   Maint By   jradigan
Test Memo

1431   04   Sink Swab

Test Type   **Surface Swab**
Site Desc   **Sink**
Category   **Viable**

Classification
Class 10,000

	Max		Min
One Side **Yes**	Alert Limit	**16.000**	**0.000**
	Action Limit	**24.000**	**0.000**

Test SOP   JJ3456-R5
Lot Specific   No
Maint Date   9/30/99   Maint By   jradigan
Test Memo

Picture

CSSC Pharmaceuticals

Environmental Monitoring System

10/20/99

ID	Description	IncT mp	Inc Hours	TNTC Val	Last Maint By	Test Cod D sc
	Test SOP	Test Media			Last Maint Date	Icon Fil Nam
1	Rodac TSA Plate	33-37	168	100	jradigan	Viable
		TSA			10/19/99 5:53:08AM	RODAC.ICO
2	Rodac Plates RB	50-55	168	300	jradigan	Viable
		Rose Bengal			10/19/99 5:55:19AM	RCS.ico
3	RCS Air Sample	33-37	120	300	jradigan	Viable
		TSA			10/19/99 5:55:24AM	RCS.ico
4	RCS Air Sample RB	50-55	120	300	jradigan	Viable
		Rose Bengal			10/19/99 5:55:30AM	RCS.ico
5	Non Viable Particulate	None	0	0	jradigan	NonViable
		None			8/19/99 5:41:45AM	Particle.ico
7	Water TOC	33-37	120	300	jradigan	Water
		TSB			8/19/99 5:41:50AM	TOC.ico
8	Touch Plate	33-37	168	300	jradigan	Viable
		TSA			8/19/99 5:41:56AM	Touch.ico
9	Settling Plate	33-37	168	300	jradigan	Viable
	ddddddd	TSA			8/19/99 5:42:02AM	Settle.ico
10	Fallout Plate	33-37	120	300	jradigan	Viable
		TSA			8/19/99 5:42:07AM	SAS.ico
11	STA Plate	33-37	120	300	jradigan	Viable
		TSA			8/19/99 5:42:12AM	STA.ico
12	Surface Swab	33-37	168	300	jradigan	Viable
		TSA			10/5/99 11:30:44AM	Swab.ico
14	SAS Air Sample	33-37 C	168	300	jradigan	Viable
		TSA			8/19/99 5:42:22AM	SAS.ico
15	Garment Sample	33-37	120	300	jradigan	Viable
		TSA			8/19/99 5:42:26AM	Gown.ico

Environmental Monitoring System

10/20/99

ID	D scription	IncT mp	Inc Hours	TNTC Val	Last Maint By	Test Code Desc
	Test SOP	Test Media			Last Maint Date	Icon Fil Nam
16	Water Endotoxin	36-38	4	5	jradigan	Water
	None				8/19/99 5:42:31AM	LAL.ico
17	Water Microbial	33-37	120	300	jradigan	Water
	TSA				8/19/99 5:42:34AM	WATER.ICO
18	Water pH	None	0	14	jradigan	Water
	None				8/19/99 5:42:39AM	ChemGen.ico
19	Water Metals	None	0	0	jradigan	Water
	None				8/19/99 5:42:45AM	WATER.ICO
20	Water Conductivity	None	0	5000	jradigan	Water
	None				8/19/99 5:42:49AM	ChemGen.ico
21	Water Coliform	None	0	300	jradigan	Water
	None				9/16/99 8:45:19AM	MicroGen.ico
22	test	88	168	30	jradigan	Viable
	jmj				8/19/99 5:42:54AM	Rodac2.ico

Environmental Monitoring System

Report Date: 10/20/99

Facility ID: **2**   Facility Name: **EMS Test Facility**

Group ID	Group Description	Frequency	Lot Specific	Group Active	Random Pick	Picks Per Survey	Last Maint Date	Last Maint By
2	Weekly Tests	Weekly	No	No	No	5	8/31/99	jradigan
3	Daily Tests	Daily	Yes	No	No	10	8/26/99	jradigan
19	Production Daily	Daily	Yes	Yes	No	10	9/17/99	jradigan

Survey Groups

CSSC Pharmaceuticals

Group Assignments

Facility: **EMS Test Facility**

Daily Tests			Group ID	3

Micro Gowning Area

MicroGowning

Non Viable Particulate

Test ID	Test ID User Ref	Test Site Description
36	P1	Particulate count taken in center of wash area.
37	P2	Particulate count taken in center of clean area.

RCS Air Sample

Test ID	Test ID User Ref	Test Site Description
34	R1	RCS airborne contamination sample taken in center of wash area.
35	R2	RCS airborne contamination sample taken in center of clean area.

Surface Swab

Test ID	Test ID User Ref	Test Site Description
32	S1	Swab sample within sink 1.
33	S2	Swab sample within sink 2.

Micro Sterility Suite

MicroSterility

Non Viable Particulate

Test ID	Test ID User Ref	Test Site Description
45	P1	Particulate count taken in room center.

Rodac TSA Plate

Test ID	Test ID User Ref	Test Site Description
38	F1	Floor site in front of laminar flow hood.
39	F2	Floor site in doorway - room entrance.
40	F3	Floor site in room corner - general cleanliness assessment.
41	E1	Site on work surface of laminar flow hood.

STA Plate

Test ID	Test ID User Ref	Test Site Description
44	1	STA airborne contamination sample taken in room center.

Touch Plate

Test ID	Test ID User Ref	Test Site Description
42	1	Touch plate taken within laminar flow hood.

Water pH

Test ID	Test ID User Ref	Test Site Description
1432	WFI-000-1	Point Of Use site at WFI Drop

Weekly Tests			Group ID	2

Micro Gowning Area

MicroGowning

Non Viable Particulate

Test ID	Test ID User Ref	Test Site Description

Group Assignments

Facility: **EMS Test Facility**

Weekly Tests   Group ID   2

Micro Gowning Area   MicroGowning

Non Viable Particulate

Test ID	Test ID User Ref	Test Site Description
36	P1	Particulate count taken in center of wash area.
37	P2	Particulate count taken in center of clean area.

RCS Air Sample

Test ID	Test ID User Ref	Test Site Description
34	R1	RCS airborne contamination sample taken in center of wash area.
35	R2	RCS airborne contamination sample taken in center of clean area.

Rodac TSA Plate

Test ID	Test ID User Ref	Test Site Description
25	F1	Floor site in doorway - room entrance.
26	F2	Floor site on wash side of bench designating class transition area.
27	F3	Floor site on clean site of bench designating class transition area.
28	F4	Floor site in doorway leading to controlled area.
29	W1	Wall site near doorway - room entrance.
30	W2	Wall site on near wall - general cleanliness assessment.
31	W3	Wall site near door leading to controlled area.

Surface Swab

Test ID	Test ID User Ref	Test Site Description
32	S1	Swab sample within sink 1.
33	S2	Swab sample within sink 2.

Micro Lab 1   A174

Fallout Plate

Test ID	Test ID User Ref	Test Site Description
21	1	Fallout plate within laminar flow hood.

Non Viable Particulate

Test ID	Test ID User Ref	Test Site Description
24	P1	Particulate count taken in room center.

RCS Air Sample

Test ID	Test ID User Ref	Test Site Description
22	ZZ1	Touch plate taken on work surface.

Rodac TSA Plate

Test ID	Test ID User Ref	Test Site Description
13	F1	Floor site in doorway - room entrance.
14	F2	Floor site in front of laminar flow hood.
15	F3	Floor site in doorway - to sterility suite.
16	F4	Floor site in front of sinks.
17	F5	Floor site in center of room.

CSSC Pharmaceuticals

Facility: **EMS T st Facility**

Weekly Tests   Group ID   **2**

Micro Lab 1   A174

Rodac TSA Plate

Test ID	Test ID User Ref	Test Site Description
18	E1	Site on work surface of laminar flow hood.

STA Plate

Test ID	Test ID User Ref	Test Site Description
23	1	Airborne contamination count taken in center of room.

Surface Swab

Test ID	Test ID User Ref	Test Site Description
19	S1	Swab sample within sink 1.
20	S2	Swab sample within sink 2.

Micro Lab2 A174   MicroLab2 A174

Non Viable Particulate

Test ID	Test ID User Ref	Test Site Description
12	P1	Particulate count taken between laminar flow hoods.

Rodac TSA Plate

Test ID	Test ID User Ref	Test Site Description
3	02	Floor between workstations approx 2 feet in front of work table.
4	04	Floor Between hood #1 and hood #2. Sample approx 2 feet in front.
5	03	Floor in center of room.
6	01	Floor in doorway / room entrance
8	05	Site on work surface of laminar hood 1.
9	E2	Site on work surface of laminar hood 2.

STA Plate

Test ID	Test ID User Ref	Test Site Description
11	S1	Airborne contamination STA plate in center of room.

Touch Plate

Test ID	Test ID User Ref	Test Site Description
10	T1	Personnel touch plate.

Micro Sterility Suite   MicroSterility

Non Viable Particulate

Test ID	Test ID User Ref	Test Site Description
45	P1	Particulate count taken in room center.

Rodac TSA Plate

Test ID	Test ID User Ref	Test Site Description
38	F1	Floor site in front of laminar flow hood.
39	F2	Floor site in doorway - room entrance.
40	F3	Floor site in room corner - general cleanliness assessment.

CSSC Pharmaceuticals

Environm ntal Monitoring System

Report Date: 10/20/99

Facility: **EMS Test Facility**

Weekly Tests | Group ID **2**

Micro Sterility Suite   MicroSterility

Rodac TSA Plate

Test ID	Test ID User Ref	Test Site Description
41	E1	Site on work surface of laminar flow hood.

STA Plate

Test ID	Test ID User Ref	Test Site Description
44	1	STA airborne contamination sample taken in room center.

Touch Plate

Test ID	Test ID User Ref	Test Site Description
42	1	Touch plate taken within laminar flow hood.

Production Room 100 Hallway   Prod100

Non Viable Particulate

Test ID	Test ID User Ref	Test Site Description
102	P1	Particulate count in center of room.

RCS Air Sample

Test ID	Test ID User Ref	Test Site Description
101	R1	RCS airborne contamination sample in center of room.

Rodac TSA Plate

Test ID	Test ID User Ref	Test Site Description
93	F1	Floor site near doorway to room 101.
94	F2	Floor site near doorway to room 103.
95	F3	Floor site near doorway to room 102.
96	F4	Floor site near doorway to room 104.
97	W1	Wall site near doorway to room 101.
98	W2	Wall site near doorway to room 103.
99	W3	Wall site near doorway to room 102.
100	W4	Wall site near doorway to room 104.

Production Room 101 Gowning Area   Prod101

Non Viable Particulate

Test ID	Test ID User Ref	Test Site Description
91	P1	Particulate count in center of wash area.
92	P2	Particulate count in center of clean area.

RCS Air Sample

Test ID	Test ID User Ref	Test Site Description
89	R1	RCS airborne contamination sample in center of wash area.
90	R2	RCS airborne contamination sample in center of clean area.

Rodac TSA Plate

Test ID	Test ID User Ref	Test Site Description

CSSC Pharmaceuticals

Facility: **EMS Test Facility**

Weekly Tests   Group ID   2

Production Room 101 Gowning Area   Prod101

Rodac TSA Plate

Test ID	Test ID User Ref	Test Site Description
80	F1	Floor site in doorway - room entrance.
81	F2	Floor site in wash area near bench designating class transition area.
82	F3	Floor site on clean side near bench designating class transition area.
83	F4	Floor site near door leading to controlled area.
84	W1	Wall site near doorway - room entrance.
85	W2	Wall site near sink in wash area.
86	W3	Wall site near door leading to controlled area.
87	E1	Rodac sample on bench designating class transition area.

Surface Swab

Test ID	Test ID User Ref	Test Site Description
88	S1	Swab sample within sink.

Production Room 102 Bottle Storage   Prod102

Non Viable Particulate

Test ID	Test ID User Ref	Test Site Description
79	P1	Particulate count in center of room.

RCS Air Sample

Test ID	Test ID User Ref	Test Site Description
78	R1	RCS airborne contamination sample in center of room.

Rodac TSA Plate

Test ID	Test ID User Ref	Test Site Description
73	F1	Floor site in doorway - room entrance.
74	F2	Floor site in center of room.
75	F3	Floor site in corner of room.
76	W2	Wall site near doorway - room entrance.
77	W2	Wall site on near wall above stored bottles.

Production Room 103 Bottling   Prod103

Non Viable Particulate

Test ID	Test ID User Ref	Test Site Description
71	P1	Particulate count within laminar flow curtains.
72	P2	Particulate count in center of room.

RCS Air Sample

Test ID	Test ID User Ref	Test Site Description
68	R1	RCS airborne contamination sample within laminar flow curtains.
69	R2	RCS airborne contamination sample in center of room.
70	R3	RCS airborne contamination sample in room corner near air return grate

CSSC Pharmaceuticals

Facility: **EMS Test Facility**

| **Weekly Tests** | | Group ID | 2 |

Production Room 103 Bottling   Prod103

Rodac TSA Plate

Test ID	Test ID User Ref	Test Site Description
59	F1	Floor site in doorway - room entrance.
60	F2	Floor site within laminar flow curtains near bottling equipment.
61	F3	Floor site in center of room.
62	F4	Floor site near work surface.
63	E1	Rodac sample on bottling equipment within laminar flow curtains.
64	E3	Rodac sample on door handle.
65	W1	Wall site on far wall near air return grate.
66	W2	Wall site near laminar flow curtains.
67	W3	Wall site above countertop.

Production Room 104 Capping   Prod104

Non Viable Particulate

Test ID	Test ID User Ref	Test Site Description
57	P1	Particulate count within laminar flow curtains.
58	P2	Particulate count in center of room.

Rodac TSA Plate

Test ID	Test ID User Ref	Test Site Description
47	F1	Floor site within laminar flow curtains near capper.
48	F2	Floor site in doorway - room entrance.
49	F3	Floor site between workstations near countertop.
50	F4	Floor site in room corner - general cleanliness assessment.
51	E1	Rodac site on capping equipment within laminar flow curtains.
52	E2	Rodac site on capping equipment within laminar flow curtains.
53	E3	Rodac site on production surface.
54	W1	Wall site on window near laminar flow curtains.

STA Plate

Test ID	Test ID User Ref	Test Site Description
55	S1	STA airborne contamination sample near capping equipment.
56	S2	STA airborne contamination sample in center of room.

Production Room 205 Raw Material Storage   Prod205

Non Viable Particulate

Test ID	Test ID User Ref	Test Site Description
121	P1	Particulate count in center of room.

RCS Air Sample

Test ID	Test ID User Ref	Test Site Description
120	R1	RCS airborne contamination sample in center of room.

CSSC Pharmaceuticals

Facility: **EMS T st Facility**

Weekly Tests | Group ID **2**

Production Room 205 Raw Material Storage   Prod205

Rodac TSA Plate

Test ID	Test ID User Ref	Test Site Description
115	F1	Floor site near doorway - room entrance.
116	F2	Floor site in center of room.
117	F3	Floor site near desk in corner of room.
118	W1	Wall site near doorway - room entrance.
119	W2	Wall site near stored raw materials.

Production Room 206 Personnel Prep Area   Prod206

Non Viable Particulate

Test ID	Test ID User Ref	Test Site Description
114	P1	Particulate count in center of room.

RCS Air Sample

Test ID	Test ID User Ref	Test Site Description
113	R1	RCS airborne contamination sample in center of room.

Rodac TSA Plate

Test ID	Test ID User Ref	Test Site Description
103	F1	Floor site near doorway - room entrance.
104	F2	Floor site near sinks 1 and 2.
105	F3	Floor site near sinks 2 and 3.
106	F4	Floor site near lockers and bench.
107	W1	Wall site near doorway - room entrance.
108	W2	Wall site near sink 3.
109	W3	Wall site near lockers.

Surface Swab

Test ID	Test ID User Ref	Test Site Description
110	S1	Swab sample within sink 1.
111	S2	Swab sample within sink 2.
112	S3	Swab sample within sink 3.

Production Room 207 Tablet Milling   Prod207

Non Viable Particulate

Test ID	Test ID User Ref	Test Site Description
140	P1	Particulate count within laminar flow curtains.
141	P2	Particulate count in center of room.

Rodac TSA Plate

Test ID	Test ID User Ref	Test Site Description
132	F1	Floor site within laminar flow curtains near tablet miller.
133	F2	Floor site near doorway - room entrance.
134	F3	Floor site near work surface.
135	F4	Floor site in center of room.
136	W1	Wall site near doorway - room entrance.

CSSC Pharmaceuticals

Facility: **EMS Test Facility**

Group Assignments

Weekly Tests   Group ID   **2**

Production Room 207 Tablet Milling   Prod207

STA Plate

Test ID	Test ID User Ref	Test Site Description
138	S1	STA airborne contamination sample within laminar flow curtains.
139	S2	STA airborne contamination sample in center of room.

Surface Swab

Test ID	Test ID User Ref	Test Site Description
137	S1	Swab sample on tablet milling equipment.

Production Room 208 Packaging   Prod208

Non Viable Particulate

Test ID	Test ID User Ref	Test Site Description
131	P1	Particulate count in center of room.

Rodac TSA Plate

Test ID	Test ID User Ref	Test Site Description
122	F1	Floor site near boxing equipment.
123	F2	Floor site near doorway - room entrance.
124	F3	Floor site in center of room.
125	F4	Floor site near sink.
126	W1	Wall site near doorway - room entrance.
127	W2	Wall site near boxing equipment.
128	E1	Rodac site on boxing equipment.

STA Plate

Test ID	Test ID User Ref	Test Site Description
130	S1	STA airborne contamination sample in center of room.

Surface Swab

Test ID	Test ID User Ref	Test Site Description
129	S1	Swab sample within sink.

Production Room 209 Lyophilization   Prod209

Non Viable Particulate

Test ID	Test ID User Ref	Test Site Description
153	P1	Particulate count within laminar flow curtains.
154	P2	Particulate count in center of room.

Rodac TSA Plate

Test ID	Test ID User Ref	Test Site Description
142	F1	Floor site within laminar flow curtains between lyophilizers 1 and 2.
143	F2	Floor site within laminar flow curtains between lyophilizers 2 and 3.
144	F3	Floor site in center of room.
145	F4	Floor site near work surface.
146	W1	Wall site near doorway - room entrance.

Group Assignments

Facility: **EMS Test Facility**

Weekly Tests   Group ID   **2**

Production Room 209 Lyophilization   Prod209

Rodac TSA Plate

Test ID	Test ID User Ref	Test Site Description
147	W2	Wall site above work surface.
148	E1	Equipment site on the door of lyophilizer 1.
149	E2	Equipment site on the door of lyophilizer 2.
150	E3	Equipment site on the door of lyophilizer 3.

STA Plate

Test ID	Test ID User Ref	Test Site Description
151	S1	STA airborne contamination sample within laminar flow curtains.
152	S2	STA airborne contamination sample in center of room.

Environmental Monitoring System

Report Date: 10/20/1999

Facility   **EMS Test Facility**

Room ID   **4**   Room Ref No   **A174**

Room Description   **Micro Lab 1**

Room Classification
Class 10.000

Production Area Classification
Not Classified

Microbiology
Quality Control
Laboratory 1
Class 10,000
G124

Test ID Ref	Test ID		Test Type	Classification	Site Desc	One Side	Alert Limits Min Max	Action Limits Min Max
1		Fallout plate within laminar flow hood.	Fallout Plate	Not Classified				
1		Airborne contamination count taken in center of room.	STA Plate	Not Classified	Counter	Yes	30	40
		Site on work surface of laminar flow hood.						
	F1	Floor site in doorway - room entrance.	Rodac TSA Plate	Not Classified				
	F2	Floor site in front of laminar flow hood.	Rodac TSA Plate	Not Classified	Floor			
	F3	Floor site in doorway - to sterility suite.	Rodac TSA Plate	Not Classified				
	F4	Floor site in front of sinks.	Rodac TSA Plate	Not Classified				
	F5	Floor site in center of room.	Rodac TSA Plate	Not Classified				
	P1	Particulate count taken in room center.	Non Viable Particulate	Not Classified	Counter			
	S2	Swab sample within sink 1.	Surface Swab	Not Classified				
		Swab sample within sink 2.	Surface Swab	Not Classified				
	ZZ1	Touch plate taken on work surface.	RCS Air Sample	Not Classified				

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Environmental Monitoring System

Report Date: 10/20/1999

Facility   EMS Test Facility

Room ID   5   Room Ref No   MicroLab2 A174

Room Description   Micro Lab2 A174

Room Classification
Class 10.000

Production Area Classification
Class 100

Test ID Ref	Test ID	Test Description	Test Type	Classification	Site Desc	One Side	Alert Limits Min	Alert Limits Max	Action Limits Min	Action Limits Max
01	6	Floor in doorway / room entrance	Rodac TSA Plate	Not Classified	Floor	Yes		13		15
02	3	Floor between workstations approx 2 feet in front of work table.	Rodac TSA Plate	Class 10,000	Floor	Yes		4		6
03	5	Floor in center of room.	Rodac TSA Plate	Class 100	Floor	No	0	13	0	15
04	4	Floor Between hood #1 and hood #2. Sample approx 2 feet in front.	Rodac TSA Plate	Class 10,000	Floor	Yes		10		15
05	8	Site on work surface of laminar hood 1.	Rodac TSA Plate	Class 100	Critical Surface	Yes		12		15
E2	9	Site on work surface of laminar hood 2.	Rodac TSA Plate	Not Classified	Critical Surface	No	0	12	0	15
F5	7	Floor in room corner - assess general room cleanliness.	Rodac TSA Plate	Class 10	Floor	Yes		20		30
P1	12	Particulate count taken between laminar flow hoods.	Non Viable Particulate	Not Classified	Counter	Yes		3		7
S1	11	Airborne contamination STA plate in center of room.	STA Plate	Class 100	Counter	Yes		20		30
T1	10	Personnel touch plate.	Touch Plate	Class 10	Glove	Yes		15		20

CSSC Pharmaceuticals

Environmental Monitoring System

Report Date: 10/20/1999

Facility **EMS Test Facility**

Room ID **6** Room Ref No **MicroSterility**

Room Description **Micro Sterility Suite**

Room Classification
Class 100.000

Production Area Classification
Class 100

Microbiology Quality Control Sterility Suite — Class 10000

Test ID Ref	Test ID	Test Description	Test Type	Classification	Site Desc	One Side	Alert Limits Min	Alert Limits Max	Action Limits Min	Action Limits Max
1	42	Touch plate taken within laminar flow hood.	Touch Plate	Not Classified	Glove	Yes		15		18
1	43	Fallout plate taken within laminar flow hood.	Fallout Plate	Not Classified	Critical Surface	Yes		10		15
1	44	STA airborne contamination sample taken in room center.	STA Plate	Not Classified	Counter	Yes		20		25
E1	41	Site on work surface of laminar flow hood.	Rodac TSA Plate	Not Classified	Critical Surface	Yes		15		18
F1	38	Floor site in front of laminar flow hood.	Rodac TSA Plate	Not Classified	Floor	Yes		20		25
F2	39	Floor site in doorway - room entrance.	Rodac TSA Plate	Not Classified	Floor	Yes		25		30
F3	40	Floor site in room corner - general cleanliness assessment.	Rodac TSA Plate	Not Classified	Floor	Yes		25		30
P1	45	Particulate count taken in room center.	Non Viable Particulate	Not Classified	Counter	Yes		2		5
WFI-000-1	1432	Point Of Use site at WFI Drop	Water pH	Not Classified	Water	No	6	7	6	8

CSSC Pharmaceuticals

Environmental Monitoring System

Report Date: 10/20/1999

Facility   **EMS Test Facility**

Room ID   **7**   Room Ref No   **MicroGowning**

Room Description   **Micro Gowning Area**

Room Classification
Class 10.000

Production Area Classification
Not Classified

Microbiology Quality Control Gowning Area
Class 1000 / 10000

Test ID Ref	Test ID	Test Description	Test Type	Classification	Site Desc	One Side	Alert Limits Min	Alert Limits Max	Action Limits Min	Action Limits Max
F1	25	Floor site in doorway - room entrance.	Rodac TSA Plate	Not Classified	Floor	Yes		20		40
F2	26	Floor site on wash side of bench designating class transition area.	Rodac TSA Plate	Not Classified	Floor	Yes		25		40
F3	27	Floor site on clean site of bench designating class transition area.	Rodac TSA Plate	Not Classified	Floor	Yes		15		25
F4	28	Floor site in doorway leading to controlled area.	Rodac TSA Plate	Not Classified	Floor	Yes		15		20
P1	36	Particulate count taken in center of wash area.	Non Viable Particulate	Not Classified	Counter	Yes		3		7
P2	37	Particulate count taken in center of clean area.	Non Viable Particulate	Not Classified	Counter	Yes		2		5
R1	34	RCS airborne contamination sample taken in center of wash area.	RCS Air Sample	Not Classified	Counter	Yes		40		50
R2	35	RCS airborne contamination sample taken in center of clean area.	RCS Air Sample	Not Classified	Counter	Yes		30		40
S1	32	Swab sample within sink 1.	Surface Swab	Not Classified	Work Surface	Yes		50		75
S2	33	Swab sample within sink 2.	Surface Swab	Not Classified	Work Surface	Yes		50		75
W1	29	Wall site near doorway - room entrance.	Rodac TSA Plate	Not Classified	Wall	Yes		30		45
W2	30	Wall site on near wall - general cleanliness assessment.	Rodac TSA Plate	Not Classified	Wall	Yes		50		65
W3	31	Wall site near door leading to controlled area.	Rodac TSA Plate	Not Classified	Wall	Yes		25		35

CSSC Pharmaceuticals

Environmental Monitoring System

Report Date: 10/20/1999

Facility: **EMS T st Facility**

Group Desc.	**Weekly Tests**
Survey Contol No.	_____
Survey Date:	_____
Survey Shift:	_____

Product: _____
Lot #: _____

Room ID: 4   RefNo   A174

Room Description
Micro Lab 1

Activity Level ☐ Normal
                ☐ Static

Microbiology
Quality Control
Laboratory 1
Class 10,000
G124

	Rodac TSA Plate		Test Date	Media Lot	
Test ID Ref	Test ID	Test Site Description	TestBy	Equipmet ID	Sample ID
F1	13	Floor site in doorway - room entrance.	_____	_____	_____
F2	14	Floor site in front of laminar flow hood.	_____	_____	_____
F3	15	Floor site in doorway - to sterility suite.	_____	_____	_____
F4	16	Floor site in front of sinks.	_____	_____	_____
F5	17	Floor site in center of room.	_____	_____	_____
E1	18	Site on work surface of laminar flow hood.	_____	_____	_____

	RCS Air Sample		Test Date	Media Lot	
Test ID Ref	Test ID	Test Site Description	TestBy	Equipmet ID	Sample ID
ZZ1	22	Touch plate taken on work surface.	_____	_____	_____

	Non Viable Particulate		Test Date		Reading
Test ID Ref	Test ID	Test Site Description	TestBy	Equipmet ID	Sample ID
P1	24	Particulate count taken in room center.	_____		☐

	Fallout Plate		Test Date	Media Lot	
Test ID Ref	Test ID	Test Site Description	TestBy	Equipmet ID	Sample ID
1	21	Fallout plate within laminar flow hood.	_____	_____	_____

	STA Plate		Test Date	Media Lot	
Test ID Ref	Test ID	Test Site Description	TestBy	Equipmet ID	Sample ID
1	23	Airborne contamination count taken in center of room.	_____	_____	_____

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Environmental Monitoring System

Report Date: 10/20/1999

Facility: **EMS T st Facility**

Group Desc. **Weekly Tests**
Survey Contol No. _____
Survey Date: _____
Survey Shift: _____

Product: _____
Lot #: _____

Room ID: 4   RefNo   A174

Room Description
Micro Lab 1

Activity Level   ☐ Normal
                 ☐ Static

Microbiology
Quality Control
Laboratory 1
Class 10,000

G124

STA Plate			Test Date	Media Lot	
Test ID Ref	Test ID	Test Site Description	TestBy	Equipmet ID	Sample ID

Surface Swab			Test Date	Media Lot	
Test ID Ref	Test ID	Test Site Description	TestBy	Equipmet ID	Sample ID
S1	19	Swab sample within sink 1.			
S2	20	Swab sample within sink 2.			

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CSSC Pharmaceuticals

Environmental Monitoring System

Report Date: 10/20/1999

Facility: **EMS T st Facility**

Group Desc. **We kly Tests**
Survey Contol No. _____
Survey Date: _____   Product: _____
Survey Shift: _____   Lot #: _____
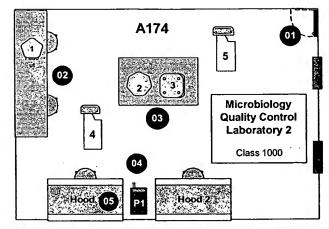
Room ID: 5   RefNo   MicroLab2 A174

Room Description
Micro Lab2 A174

Activity Level   ☐ Normal
                  ☐ Static

A174 — Microbiology Quality Control Laboratory 2 — Class 1000

Rodac TSA Plate			Test Date	Media Lot	
Test ID Ref	Test ID	Test Site Description	TestBy	Equipmet ID	Sample ID
02	3	Floor between workstations approx 2 feet in front of work table.			
04	4	Floor Between hood #1 and hood #2. Sample approx 2 feet in front.			
03	5	Floor in center of room.			
01	6	Floor in doorway / room entrance			
05	8	Site on work surface of laminar hood 1.			
E2	9	Site on work surface of laminar hood 2.			

Non Viable Particulate			Test Date		Reading
Test ID Ref	Test ID	Test Site Description	TestBy	Equipmet ID	Sample ID
P1	12	Particulate count taken between laminar flow hoods.			

Touch Plate			Test Date	Media Lot	
Emp/Tech ID	Test ID	Test Site Description	TestBy	Equipmet ID	Sample ID
	10	Personnel touch plate.			

STA Plate			Test Date	Media Lot	
Test ID Ref	Test ID	Test Site Description	TestBy	Equipmet ID	Sample ID
S1	11	Airborne contamination STA plate in center of room.			

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CSSC Pharmaceuticals

Environmental Monitoring System

Report Date: 10/20/1999

Facility: **EMS Test Facility**

Group Desc. **Weekly Tests**
Survey Contol No. _____
Survey Date: _____
Survey Shift: _____

Product: _____
Lot #: _____

Room ID: 6 RefNo MicroSterility

Room Description
Micro Sterility Suite

Activity Level [ ] Normal

[ ] Static

Microbiology Quality
Control Sterility Suite

Class 10000

Rodac TSA Plate			Test Date	Media Lot	
Test ID Ref	Test ID	Test Site Description	TestBy	Equipment ID	Sample ID
F1	38	Floor site in front of laminar flow hood.	_____	_____	_____
F2	39	Floor site in doorway - room entrance.	_____	_____	_____
F3	40	Floor site in room corner - general cleanliness assessment.	_____	_____	_____
E1	41	Site on work surface of laminar flow hood.	_____	_____	_____

Non Viable Particulate			Test Date		Reading
Test ID Ref	Test ID	Test Site Description	TestBy	Equipmet ID	Sample ID
P1	45	Particulate count taken in room center.	_____	_____	[ ]

Touch Plate			Test Date	Media Lot	
Emp/Tech ID	Test ID	Test Site Description	TestBy	Equipmet ID	Sample ID
_____	42	Touch plate taken within laminar flow hood.	_____	_____	_____

STA Plate			Test Date	Media Lot	
Test ID Ref	Test ID	Test Site Description	TestBy	Equipmet ID	Sample ID
1	44	STA airborne contamination sample taken in room center.	_____	_____	_____

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CSSC Pharmaceuticals

Environmental Monitoring System

Report Date   Wednesday, January 16, 2002

Bacteria

Genus Desc	Genus/Species ID	Organism Type	Genus/Species Name	Objectionable
Bacteria	2	1	Bacillus stearothermophilis	N
	3	1	Bacillus circulans	N
	4	1	Bacillus cereus	N
	5	1	Bacillus coagulans	Y
	6	1	Clostridium acetobutyl	N
	7	1	Pseudomonas aeruginosa	N
	8	1	Pseudomonas fluorescens	N
	9	1	Staphylococcus aureus	N
	10	1	Salmonella arizonea	N
	18	1	Bacillus subtillus	Y
	45	1	New Org ID	Y
	47	1	Test Organism	N
Total **Bacteria**		12		

Fungi

Genus Desc	Genus/Species ID	Organism Type	Genus/Species Name	Objectionable
Fungi	13	4	Fungi NOD	N
Total **Fungi**		1		

Mold

Genus Desc	Genus/Species ID	Organism Type	Genus/Species Name	Objectionable
Mold	12	3	Mold NOD	N
Total **Mold**		1		

Other

Genus Desc	Genus/Species ID	Organism Type	Genus/Species Name	Objectionable
Other	23	11	Other NOD	N
Total **Other**		1		

Yeast

Genus Desc	Genus/Species ID	Organism Type	Genus/Species Name	Objectionable
Yeast	11	2	Yeast NOD	N
Total **Yeast**		1		